

**In the United States Court of Federal Claims**

## OFFICE OF SPECIAL MASTERS

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JESSIE CONTRERAS,

Petitioner,

V.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

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No. 05-626V

Special Master Christian J. Moran

Filed: October 24, 2014

hepatitis B vaccine; tetanus-diphtheria vaccine; transverse myelitis (TM); Guillain-Barré syndrome (GBS); one-day onset; decision on remand; credibility of expert; reliability of expert.

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Jeffrey S. Pop, Jeffrey S. Pop, Attorney at Law, Beverly Hills, CA, for petitioner;  
Linda S. Renzi, United States Dep't of Justice, Washington, DC, for respondent.

## **PUBLISHED DECISION ON REMAND DENYING ENTITLEMENT<sup>1</sup>**

On June 16, 2003, Mr. Contreras received the hepatitis B vaccine and the tetanus-diphtheria vaccine. Approximately 24 hours later, he started experiencing symptoms that marked the onset of a very severe neurologic disease, transverse myelitis. Mr. Contreras claims that the vaccinations, particularly the hepatitis B vaccine, caused his neurologic problems and seeks compensation through the National Childhood Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa—10 through 34 (2006).

Judicial officials have issued four substantive rulings.<sup>2</sup> In the most recent one, the Court vacated a decision denying compensation and remanded for more

<sup>1</sup> The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

specific findings of fact with respect to the experts' credibility. This additional fact-finding was necessitated by the revelation that Dr. Sladky, one of the two experts who testified on behalf of the Secretary, misrepresented his background and failed to disclose problems in his medical licensing. The dimensions of Dr. Sladky's misdeeds are set forth in a review of the procedural history of this case, which is Section I below.

The remainder of the Decision attempts to respond to the Court's three instructions. First, the Court required an "unambiguous assessment" of Dr. Sladky's credibility and reliability. For the reasons discussed in Section II, Dr. Sladky was not credible regarding his background, but credible for his substantive opinions. His substantive opinions were reliable because they were based upon a sound methodology. Second, the Court required an evaluation of the credibility of all the testifying experts and a comparison among them. Section III explains that Dr. Sladky's credibility was less than all but one of the other testifying doctors. Third, the Court directed an assessment of the issues without regard for Dr. Sladky's evidence. Section IV reviews the evidence regarding diagnosis, timing, theory, and logical sequence of cause and effect. Excluding Dr. Sladky's evidence does not change the outcome.

Consequently, Mr. Contreras remains not entitled to compensation. The Clerk's Office is directed to enter judgment in accord with the decision unless another motion for review is filed.

## **I. Procedural History Focused on Dr. Sladky's Misconduct**

On June 15, 2005, Mr. Contreras filed his petition. With it, Mr. Contreras filed medical records and statements from three doctors who treated him, Dr. Fred Kyazze, Dr. Mark Wagner, and Dr. Jeremy Garrett. Exhibits 11-13. Dr. Garrett identified Mr. Contreras's injury as "cervical transverse myelitis" and opined that the hepatitis B vaccination caused the transverse myelitis. Exhibit 13 at 4 ¶ 7, 7 ¶

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<sup>2</sup> An April 5, 2012 Entitlement Decision denied compensation because Mr. Contreras did not meet his burden of proof regarding the appropriate interval between vaccination and the onset of the transverse myelitis. 2012 WL 1441315 ("Contreras 1"). The United States Court of Federal Claims ("the Court") vacated this decision and remanded with instructions. 107 Fed. Cl. 280 (2012) ("Contreras 2"). A November 19, 2013 Remand Decision again denied compensation. 2013 WL 6698382 ("Contreras 3"). The Court also vacated the Remand Decision. 116 Fed. Cl. 472 (2014) ("Contreras 4").

Citations to Contreras 3 will include both the page number to the version published on Westlaw and, to maintain consistency with Contreras 4, the page number of the slip opinion.

12 (“[Mr. Contreras’s] diagnosis was thus established as transverse myelitis”), 13 ¶ 17. In addition, Mr. Contreras submitted an affidavit from Dr. Charles Poser. Dr. Poser, unlike Dr. Garrett, stated that Mr. Contreras suffered from Guillain-Barré syndrome and transverse myelitis. Yet, like Dr. Garrett, Dr. Poser also proposed that the vaccinations caused the Guillain-Barré syndrome and transverse myelitis. Exhibit 22 at 3 ¶ 4-5. Dr. Poser found a causal relationship despite “[t]he very short latency of the neurological complications following the vaccination,” which Dr. Poser acknowledged was “unusual.” *Id.* at ¶ 5. Dr. Poser did not otherwise propose a mechanism by which a vaccine can cause a neurologic injury in one day. See exhibit 22. Dr. Poser, later, authored another affidavit, expanding upon the bases for his assertion that the vaccines can cause neurologic injury. Exhibit 23.

On October 27, 2005, the Secretary filed her report, pursuant to Vaccine Rule 4. Before submitting Dr. Sladky’s first report, the Secretary raised the issue of timing. Citing a 1994 report from the Institute of Medicine (IOM), the Secretary asserted that “a plausible interval between vaccination and the onset of symptoms is 5-45 days.” Resp’t’s Rep’t, filed Oct. 7, 2005, at 9.<sup>3</sup> The Secretary argued that Dr. Poser “offers no explanation as to how [Mr. Contreras’s] condition could plausibly evolve within [24 hours]. Even the case studies referred to by Dr. Poser do not describe symptoms immediately following vaccination.” *Id.* at 10. The Secretary’s report concluded by maintaining that “the temporal relation between vaccination and the onset of [Mr. Contreras’s] illness does not support the conclusion that [Mr. Contreras’s] condition was caused by the administration of the Hepatitis B vaccine; in fact, it supports the opposite,” and committed to submit an expert report. *Id.*

The Secretary filed a report from Dr. Sladky dated October 21, 2005, and his curriculum vitae (“CV”), which were initially labelled as exhibits A and B. These appear in the record as exhibit I and exhibit J.

Dr. Sladky’s CV contained an error when it was submitted. Dr. Sladky asserted that he was licensed to practice medicine in two states, Pennsylvania and Georgia. However, it is now known that Dr. Sladky’s license in Pennsylvania had expired in 1996, nine years earlier. The Court commented “Dr. Sladky’s CV,

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<sup>3</sup> The Secretary’s report contains two minor errors. First, while the Secretary recounts the IOM’s estimate for latency as “5-45 days,” the IOM actually states “5 days to 6 weeks.” Second, although the Secretary’s report accurately cites pages 37-49 of the 1994 IOM report (a more precise citation is to page 45 and/or 47), the Secretary did not include those pages within the document she actually submitted as exhibit A. She later filed pages 45-46 as exhibit F.

bearing no notation that his license in Pennsylvania had expired, misrepresented Dr. Sladky's credentials. Thus, the expert report filed by Dr. Sladky in 2005 was supported by an inaccurate and misleading CV." Contreras 4, 116 Fed. Cl. at 477.

Dr. Sladky's error in presenting his qualifications appears not to have carried over to his report. There is no evidence or allegation that Dr. Sladky's first report was erroneous in any respect. Dr. Sladky's first report emphasized the timing was not appropriate for causation. He stated "the brief interval between the hepatitis B vaccine administration and the onset of symptoms of transverse myelitis in Jessie Contreras is the most compelling evidence that immunization and demyelinating disease, in this instance, are purely coincident." Exhibit I at 3. He explained "[a]utoimmune demyelinating disorders such as transverse myelitis are caused by a complex cascade of immunological events ultimately acting in concert to cause injury to constituents of the central nervous system." Id.<sup>4</sup> Dr. Sladky then asserted "[i]t is virtually impossible to believe that the intricate process of immune activation, tissue targeting and ultimately immunologic attack on the nervous system could occur within a 24 hour interval." Id. Dr. Sladky's basis was the 1994 IOM article that found that "the duration from immunization to onset of symptoms should fall between 5 days at a minimum and 6 weeks at maximum to conform to biological plausibility." Id. He also described the basis for the 1994 IOM findings, noting that the IOM used animal models. Id. at 4-5 (citing exhibit K (Divya J. Mekala et al., IL-10-dependent Infectious Tolerance After the Treatment of Experimental Allergic Encephalomyelitis with Redirected CD4<sup>+</sup>CD25<sup>+</sup> T Lymphocytes, 102(33) PNAS 11817 (2005)); and exhibit D (E.P.K. Mensah-Brown et al., Neuroglial Response After Induction of Experimental Allergic Encephalomyelitis in Susceptible and Resistant Rat Strains, 233 Cellular Immunology 140 (2005))).

Thus, in 2005, timing was an important issue. Dr. Poser flagged the issue in his first report, describing the latency as "unusual." Exhibit 22 at 3 ¶ 5. The Secretary raised this issue in her Rule 4 Report. Resp't's Rep't, filed Oct. 7, 2005, at 9. Separately, Dr. Sladky raised it in his October 21, 2005 report. Exhibit I. Significantly, both the Secretary and Dr. Sladky relied upon the 1994 IOM report. In the ensuing status conference, the then-presiding special master also discussed the 1994 IOM report as well as Dr. Sladky's opinion. The then-presiding special master stated "whether there exists an adequate basis, grounded in principles of

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<sup>4</sup> Testimony from Dr. Steinman and Dr. Whitton elaborated on the concept of the "complex cascade of immunological events." See Tr. 123-38, 237-40, 413-23, 441-43.

immunology, for the special master to find that the interval of less than 24 hours... medically appropriate” may be a “potentially dispositive issue.” Order, filed Nov. 18, 2005, at 2.<sup>5</sup>

The then-presiding special master’s response to the Secretary’s report and Dr. Sladky’s report was to order Mr. Contreras to file a medical opinion from an “immunologist or a neuroimmunologist.” Id. Mr. Contreras presented Dr. Steinman’s first report on March 9, 2006. Exhibit 55. Dr. Steinman compared Mr. Contreras’s asserted reaction to the vaccinations to a reaction to tuberculin. In Dr. Steinman’s view because the latter reaction can take place in 24 hours, the former reaction can happen in 24 hours as well. Id. at 3.

Following the submission of Dr. Steinman’s report, the formal progression of Mr. Contreras’s litigation largely stalled. Instead, the parties attempted to resolve the dispute using alternative dispute resolution (“ADR”).

During this interlude in the formal litigation, on August 19, 2008, Dr. Sladky agreed not to practice medicine in Georgia while he was treated for alcohol dependence. Resp’t’s Status Rep’t, filed May 1, 2013, at 4; see also Contreras 4, 116 Fed. Cl. at 476. Dr. Sladky, apparently, did not inform the Secretary that he had agreed not to practice medicine because the Secretary did not disclose this information until 2013. At the hearing, Dr. Sladky testified that he did not work on Mr. Contreras’s case in 2008 or 2009. Tr. 321.

The then-chief special master conducted an ADR session on September 3, 2008. However, the parties did not resolve their differences. Accordingly, the parties resumed pursuing a formal resolution of Mr. Contreras’s petition for compensation. As the first step in this renewed process, the Secretary was ordered to file a response to Dr. Steinman’s report. Orders, filed Apr. 3, 2008, Jan. 21, 2009, and Feb. 10, 2009. The Secretary did not rely upon Dr. Sladky, who had previously opined in this case. Instead, the Secretary opted to retain Dr. Whitton, who has extensive experience in immunology. See exhibit M (CV).

In 2009, the parties exchanged a series of reports written by Dr. Whitton and Dr. Steinman. Exhibit L (Dr. Whitton’s Rep’t, filed Feb. 19, 2009); exhibit 105

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<sup>5</sup> While Mr. Contreras’s case was pending, the presiding special master adopted the 5-42 day interval between the introduction of an antigen and the development of a demyelinating disease of the central nervous system. Fant v. Sec’y of Health & Human Servs., No. 02-1419V, 2007 WL 5161767, at \*11 (Fed. Cl. Spec. Mstr. Mar. 9, 2007).

(Dr. Steinman's Supp'l Rep't, filed June 29, 2009); exhibit N (Dr. Whitton's Supp'l Rep't, filed Sept. 8, 2009). In this back and forth, Dr. Whitton opined that one day was not a sufficient amount of time to cause transverse myelitis and Dr. Steinman maintained that it was. The Secretary's continued use of Dr. Whitton in 2009 led to a question about whether the Secretary was maintaining her reliance on Dr. Sladky.

Meanwhile, as the parties were exchanging expert reports, there were additional (unknown) developments with Dr. Sladky. Less than one year after he voluntarily relinquished his medical license on a temporary basis, Dr. Sladky's dependence on alcohol was the basis for a more serious action by the Georgia Composite State Board of Medical Examiners. On June 19, 2009, the Georgia Board suspended Dr. Sladky's license indefinitely. Resp't's Status Rep't, filed May 1, 2013, at 4; see also Contreras 4, 116 Fed. Cl. at 476. Again, the Secretary's disclosure of this suspension came in 2013, approximately four years after it occurred.<sup>6</sup>

On January 8, 2010, a status conference was held. It appeared that before the interlude for ADR, the Secretary had been relying upon the opinion of Dr. Sladky to respond to Dr. Poser, but after the litigation resumed, it appeared that the Secretary was relying upon the opinion of Dr. Whitton as the Secretary had not obtained a report from Dr. Sladky in response to Dr. Steinman's report. Thus, during the January 8, 2010 status conference, the parties discussed whether the Secretary intended to present testimony from Dr. Sladky at the forthcoming hearing. During this status conference, the Secretary apparently was ignorant of the Georgia Board's suspension of Dr. Sladky's license.

In response to the order from the January 8, 2010 status conference, the Secretary disclosed that she intended to call Dr. Sladky at the hearing. In this context, the Secretary stated, "Dr. Sladky is preparing a supplemental expert report to address the issues raised by petitioner's expert, Dr. Steinman. Respondent will file Dr. Sladky's report, an updated curriculum vitae, and referenced medical articles, no later than March 8, 2010." Resp't's Status Rep't, filed Jan. 27, 2010, at 1; accord Contreras 4, 116 Fed. Cl. at 477. The Court's recitation of this status report emphasized that respondent recounted Dr. Sladky "is preparing" a supplemental report.

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<sup>6</sup> The Georgia Board's suspension was a public consent order that is, now, available through a website. Whether the Georgia Board made this order available to the public through its website in 2009 is not known.

The Court cited the phrase “is preparing” as one piece of evidence that showed Dr. Sladky was working on his supplemental report while his license to practice medicine in Georgia was suspended. Other evidence supporting the same proposition were “the detailed analysis of Dr. Steinman’s opinions in Dr. Sladky’s second expert report” and “the date marked on Dr. Sladky’s report, March 4, 2010.” Contreras 4, 116 Fed. Cl. at 477.

On March 4, 2010, the Georgia Board issued another Public Consent Order. The Georgia Board restored Dr. Sladky’s medical license on a probationary basis. The Georgia Board conditioned Dr. Sladky’s retention of his license on several factors, including continued participation in support groups for alcoholics, supervision by another doctor, and restrictions on the number of hours and location of his practice. Resp’t’s Status Rep’t, filed May 1, 2013, at 4-13.

March 4, 2010, is also the date at the top of Dr. Sladky’s supplemental expert report. The Secretary filed this report, which is exhibit O, on March 8, 2010. The original submission lacked a signature. The Secretary submitted another copy of the report dated March 4, 2010, still labelled as exhibit O, on March 22, 2010. Dr. Sladky signed the second version.

Dr. Sladky’s supplemental report, exhibit O, matched his initial report, exhibit I, with respect to his ultimate opinion --- that there was no evidence to support the conclusion that the vaccinations caused Mr. Contreras’s transverse myelitis. The primary basis for Dr. Sladky’s opinion --- that the timing was insufficient --- remained the same.

Dr. Sladky did not reveal in his reports dated March 4, 2010, that the Georgia Board had suspended his license and had restored his license to a probationary status on the same day as he dated his report. The Court also noted that the supplemental report remained “supported by an inaccurate and misleading CV as to licensure in Pennsylvania.” Contreras 4, 116 Fed. Cl. at 477. The Court also stated that “[t]here is no information in the record which explains why respondent never filed an updated CV for Dr. Sladky to accompany his second expert report, as promised in the January 27, 2010 status report.” Id.

On April 20, 2010, Dr. Sladky testified at the hearing held in California. The Secretary asked general questions about Dr. Sladky’s background. Dr. Sladky stated that he was employed in the Department of Pediatric Neurology at Emory University. Tr. 274-75. He elaborated:

I'm senior faculty in pediatric neurology at Emory. I see patients. I do a little bit of research. That's become markedly attenuated as I get eaten by the clinical monster as I think the rest of us are. And I teach medical students, residents and fellows.

I see patients every week, usually five half days a week, probably average 40-50 patients a week, and attend on the inpatient neurology service roughly three months a year, a little less. And during those periods, I have very hectic months very much like the one Dr. Steinman just survived. Congratulations, incidentally. We look at those as benchmarks in moving along life. Pretty standard, busy clinical and academic lifestyle.

Tr. 275. Dr. Sladky also provided information about his undergraduate education (Yale University), his medical school (also Yale University), and fellowship training (University of Pennsylvania). He stated he was board-certified in pediatrics, neurology with a special competence in child neurology, and electro-diagnostic medicine. Tr. 276. When the Secretary offered Dr. Sladky as an expert witness in the area of pediatric neurology, the Secretary referenced Dr. Sladky's CV, exhibit J, which had been filed in 2005. Tr. 278.

The Court noted that Dr. Sladky's description of his responsibilities regarding seeing 40-50 patients per week was "misleading." The Court determined that in "the two-year period of time leading up to this testimony, Dr. Sladky was licensed to practice medicine for eight and a half of those twenty-four months, and more than one month of the time that he was licensed to practice medicine during that period was under supervised probation." Contreras 4, 116 Fed. Cl. at 479.

When given an opportunity to ask questions about Dr. Sladky's background on voir dire, petitioner's counsel declined. Tr. 278. As the Court noted,

[Dr. Sladky] did not state, and was not asked to state, whether he was licensed to practice medicine in Pennsylvania and Georgia. He was not asked whether his license to practice medicine was on probation (which it was at the time he testified), and he was not asked whether he had been subject to disciplinary proceedings which led to the suspension of his license.



Contreras 4, 116 Fed. Cl. at 479.

At the hearing, there was relatively little testimony from Dr. Sladky about the medically acceptable interval between vaccination and the onset of transverse myelitis. The Secretary elicited some as part of Dr. Sladky's direct examination. Tr. 310.<sup>7</sup> On cross-examination, Mr. Contreras asked Dr. Sladky about his opinion regarding the minimal amount of time for an immune-mediated response. Tr. 329-30. Otherwise, Dr. Sladky's testimony was on other topics, including how Hispanics respond to vaccinations.

Instead of using Dr. Sladky, the Secretary presented testimony from Dr. Whitton about the immune system and how long the immune system requires to generate a response that could lead to transverse myelitis. In support of his opinion, Dr. Whitton testified about many articles, including Lafaille, Zamvil, and Kakar. See Tr. 424-37, 441-43 (discussing exhibit 77 (Juan J. Lafaille, Myelin Basic Protein-specific T Helper 2(Th2) Cells Cause Experimental Autoimmune Encephalomyelitis in Immunodeficient Hosts Rather than Protect Them from the Disease, 186(2) J. Experimental Med. 307 (1997)); exhibit 67 (Scott Zamvil et al., T-cell Clones Specific for Myelin Basic Protein Induce Chronic Relapsing Paralysis and Demyelination, 317 Nature 355 (1985)); exhibit 72 (Atul Kakar & P.K. Sethi, Guillain Barre Syndrome Associated with Hepatitis B Vaccination, 64(5) Indian J. Pediatrics 710 (1997))). Dr. Whitton was asked follow-up questions about the anticipated interval. See Tr. 455-56, 462-64, 477-85.

After the parties submitted a set of briefs, it appeared that the Odoardi article could potentially assist Mr. Contreras in establishing that one day was an appropriate interval. Exhibit 118 (F. Odoardi et al., Blood-borne soluble protein antigen intensifies T cell activation in autoimmune CNS lesions and exacerbates clinical disease, 104(47) PNAS 18625 (2007)). While both Dr. Steinman and Dr. Whitton had testified about Odoardi during the April 2010 hearing, their testimony seemed incomplete. See Tr. 175 (Dr. Steinman), 243-46 (same) 479-82 (Dr. Whitton). Consequently, the undersigned requested another hearing to hear testimony from Dr. Steinman and Dr. Whitton. Order, filed June 6, 2011; see also Contreras 2, 107 Fed. Cl. at 289 n.19 (the topic of the second hearing "is indicative of the special master's increasing focus on Dr. Steinman's and Dr. Whitton's diverging opinions as to the science relevant to determine a medically-appropriate

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<sup>7</sup> Dr. Sladky also discussed the onset of Mr. Contreras's neurologic problem, Tr. 279-81, but the precise number of hours between vaccination and onset has never been a material fact.

timeframe for the onset of Jessie's illness"). Dr. Sladky did not participate in this hearing because his expertise was not in immunology on which timing is based.

After this second hearing, the case was submitted for adjudication. Mr. Contreras was found not entitled to compensation because he had not established that 24 hours is an appropriate temporal interval between vaccination and the onset of symptoms. Contreras 1, 2012 WL 1441315 (Fed. Cl. Spec. Mstr. Apr. 5, 2012).<sup>8</sup>

Mr. Contreras filed a motion for review, which was granted. The April 5, 2012 entitlement decision was vacated and the case was remanded. Contreras 2, 107 Fed. Cl. 280.

While on remand, on May 1, 2013, the Secretary disclosed much of the detrimental information about Dr. Sladky to Mr. Contreras and to the Office of Special Masters.<sup>9</sup> The Secretary's citation to Shaffer Equip. Co. v. United States, 11 F.3d 450, 458-59 (4th Cir. 1993), suggested that the Secretary understood that she was obligated to reveal information about her expert's background once she learned of the misrepresentations. Specifically, the Secretary revealed

Respondent has become aware that Dr. Sladky agreed not to practice medicine in the state of Georgia from August 19, 2008 to March 18, 2009, and agreed to the indefinite suspension of his license to practice medicine on June 17, 2009, and that on March 4, 2010, the suspension of his license was lifted and his license to practice restored on a probationary basis. The probation was terminated on July 5, 2011. The details of the suspensions and probation are set forth in the attached public orders of the Georgia Composite Medical Board.

Resp't's Status Rep't., filed May 1, 2013, at 1. In this status report, the Secretary did not reveal that Dr. Sladky's medical license for Pennsylvania had expired in 1996.

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<sup>8</sup> Section IV below discusses the reasoning in the Entitlement Decision in greater detail.

<sup>9</sup> The Secretary filed substantively the same status report in every active case in which Dr. Sladky had submitted a report. For closed cases, the Secretary submitted a letter notifying the petitioner and the presiding special master of Dr. Sladky's licensure issues.

Mr. Contreras, however, discovered the misrepresentation on Dr. Sladky's 2005 CV. Mr. Contreras presented evidence from the Pennsylvania Department of State that Dr. Sladky's license to practice medicine in that state expired on December 31, 1996. Pet'r's Status Rep't, filed May 10, 2013, at exhibit 2. In response to Shaffer Equip., Mr. Contreras appeared to acknowledge that his case was different in the sense that there was no evidence that the Secretary or her attorneys actually knew of Dr. Sladky's licensing problems. Pet'r's Status Rep't, filed May 10, 2013, at 4-5. Mr. Contreras proposed that the "Special Master should find that [Dr.] Sladky's opinion and conclusion carry little, if any[,] weight, due to the circumstances under which he was providing testimony." Id. at 9. Mr. Contreras did not propose striking Dr. Sladky's evidence.

The Secretary was permitted to respond to Mr. Contreras's arguments regarding Dr. Sladky as part of her brief on remand. The Secretary mostly addressed accusations about Dr. Sladky that Mr. Contreras did not substantiate, but the Secretary did not address the accusation about Dr. Sladky's Pennsylvania license that Mr. Contreras did substantiate. The Secretary concluded that:

[T]he opinion[] of . . . Dr. Sladky [is] based upon sound scientific principles that were clearly articulated at hearing and supported by the medical literature. Respondent's disclosure of the temporary suspension and later probationary status of Dr. Sladky's license . . . should not be used to circumvent the fact that petitioner has failed to prove causation.

Resp't's Resp., filed June 12, 2013, at 39.

Mr. Contreras had the last word, repeating some of the problems with Dr. Sladky. Pet'r's Reply, filed Aug. 13, 2013, at 31-34. The reply brief argued that Dr. Sladky's testimony should be "scrutinized and given diminished importance." Id. at 34.

On November 19, 2013, a 76-page decision on remand denied entitlement. Approximately two and half pages were devoted to Dr. Sladky's background. Ultimately, the remand decision concluded that "Dr. Sladky's opinions retain some value." Contreras 3, slip op. at 7, 2013 WL 6698382, at \*5. Dr. Sladky's name appears in the remand decision in approximately 20 places, which are discussed at length below. The Remand Decision included a statement that the analysis

contained therein “does not rely upon Dr. Sladky’s opinion extensively.” Contreras 3, slip op. at 71 n.51, 2013 WL 6698382, at \*55 n.51.

Mr. Contreras filed a second motion for review. In his objections, Mr. Contreras argued, among other things, that:

The Special Master heavily relied on the testimony of Dr. Sladky, despite the fact that Dr. Sladky has been discredited and failed to disclose to the Court and Counsel that his medical license was suspended and later he was on probation due to alcohol abuse problems at times he rendered his opinions.

Pet’r’s Second Mot. for Rev., filed Dec. 19, 2013, at 2. This objection was developed as the first argument in the motion for review.

After summarizing Dr. Sladky’s faults, Mr. Contreras concluded: “Dr. Sladky’s lack of transparency and untruthfulness is appalling. He could not actually see patients if he was suspended. Dr. Sladky’s medical license suspension and later probation with restrictions when he testified is relevant. His incorrect C.V. bears on his character and critically undermines his credibility as an expert.” Id. at 5. Mr. Contreras’s motion for review argued that the Remand Decision’s statement that “Dr. Sladky’s opinions retained ‘some’ value is a misnomer.” Id. However, Mr. Contreras’s second motion for review did not argue for striking Dr. Sladky’s opinion entirely.

In deciding the second motion for review, the Court reviewed the disclosures that the Secretary made regarding Dr. Sladky’s licensing in Georgia and the information Mr. Contreras presented regarding Dr. Sladky’s licensing in Pennsylvania. In addition, the Court reviewed information that Dr. Sladky had presented in other cases, including Roberts v. Sec’y of Health & Human Servs., No. 09-427V, 2013 WL 5314698 (Fed. Cl. Spec. Mstr. Aug. 29, 2013), and Raymo v. Sec’y of Health & Human Servs., No. 11-654V, 2014 WL 1092274 (Fed. Cl. Spec. Mstr. Feb. 24, 2014). Contreras 4, 116 Fed. Cl. at 480. The Court vacated the November 19, 2013 Remand Decision and ordered another decision that more explicitly discusses Dr. Sladky’s credibility and reliability. Id. at 484.

Upon remand, the parties were again ordered to file briefs. Order, issued May 27, 2014. The Secretary’s brief, as discussed more thoroughly in section II.A below, focused more upon the reliability of Dr. Sladky’s opinions and less upon the credibility of Dr. Sladky. Resp’t’s Resp., filed June 23, 2014. Mr. Contreras

also filed a response. His primary argument was that “Dr. Sladky’s testimony must be completely disregarded.” Pet’r’s Resp., filed July 21, 2014, at 1 (capitalization changed without notation). This request from relief differed from the remedy (increased scrutiny) for which Mr. Contreras previously advocated. See Pet’r’s Reply, filed Aug. 13, 2013, at 34.<sup>10</sup> Mr. Contreras argued that the result in his case should match the outcome in Raymo. Pet’r’s Resp., filed July 21, 2014, at 3. Beyond citing Raymo, Mr. Contreras did not cite other cases, not even Roberts, a case in which the special master considered Dr. Sladky’s evidence but found it unpersuasive.

Mr. Contreras’s July 21, 2014 response additionally discussed the substantive issues in his case. For example, Mr. Contreras maintained that he suffered from both Guillain-Barré syndrome and transverse myelitis. He also argued that he had established that the hepatitis B vaccine caused his neurologic injuries. Pet’r’s Resp., filed July 21, 2014, at 6-13.

A status conference was held on July 30, 2014. The parties indicated that they did not wish to submit additional information. Thus, the case is again ready for adjudication.

The remainder of this decision is organized into three large sections with each section corresponding to a specific question the Court asked. The first section addresses Dr. Sladky’s credibility and reliability. This section also encompasses an evaluation of Mr. Contreras’s motion to strike Dr. Sladky’s evidence. The next section compares Dr. Sladky’s credibility to other witnesses who testified either by affidavit or in person. The third section assumes that Dr. Sladky’s evidence is not part of the case and evaluates the remaining evidence. Before the conclusion, there is a short section presenting “additional comments.”

## **II. Dr. Sladky’s Credibility and Reliability**

### **A. Background, including Court’s Instructions and Parties’ Arguments**

After the Secretary disclosed Dr. Sladky’s alcohol problem and consequent licensing problems in Georgia, Mr. Contreras discovered the additional

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<sup>10</sup> Mr. Contreras could justify his changed position because the Court’s June 16, 2014 Opinion and Order revealed details about Dr. Sladky’s misrepresentations in other cases about which Mr. Contreras was previously uninformed.

misrepresentation on Dr. Sladky's CV concerning the expiration of his Pennsylvania license. See Pet'r's Status Rep't, filed May 10, 2013. Mr. Contreras concluded his submission by arguing that his testimony should be "scrutinized and diminished." Id. at 10.

The Remand Decision stated that Dr. Sladky's opinion retained "some value" (page 7) and added, in the context of the discussion regarding timing, "the problems in Dr. Sladky's licensing and the non-disclosure of these problems ha[ve] minimal effect on this case." Contreras 3, slip op. at 7, 71 n.51, 2013 WL 6698382, at \*55 n.51. The Court held that this assessment was "ambiguous." Contreras 4, 116 Fed. Cl. at 481.

In directing the scope of the remand, the Court stated the special master "must first determine whether or not Dr. Sladky is a credible witness providing reliable opinions." Id. at 483. The Court ordered the special master to "provide an unambiguous estimation of Dr. Sladky's credibility and reliability as an expert." Id. at 484. The Court instructed:

A distinction should be drawn between the content of Dr. Sladky's opinions, which may match the special master's view of the case, and the credibility of Dr. Sladky as an expert who provided two expert reports and testimony in this case. In essence, the question of credibility focuses on whether Dr. Sladky was a reliable source of expert opinion, not whether his opinions . . . were persuasive.

Id. at 484 n.12 (emphasis in original). Further, it appears that the Court expects that Dr. Sladky's credibility will be evaluated before the substance of his opinion is weighed because, it appears, that if Dr. Sladky is not credible as a person, then his opinion would be rejected entirely.

The Secretary's most recent brief seems to miss this distinction between the credibility of a person and the reliability of the opinion a person offers. The Secretary asserted that "[i]n assessing the credibility of an expert witness, factors such as education, board certification, academic achievements, publications and clinical experience are relevant." Resp't's Resp., filed June 23, 2014, at 4. These factors, in the Secretary's view, are also relevant in determining "whether the expert possesses the underlying expertise to render an accurate and reliable opinion. . . . No matter how qualified an expert is, his opinion is only as reliable as the underlying scientific principles on which he relies." Id. The Secretary's

confusion between credibility and reliability is also evident later when the Secretary argued that “[i]n assessing the credibility and reliability of Dr. Sladky’s opinion in unambiguous terms, an emphasis should be placed on Dr. Sladky’s professional qualifications and experience to offer a reliable opinion.” *Id.* at 8.

What is missing from the Secretary’s list of factors to consider in assessing a person’s credibility is, perhaps, the most basic aspect. Did the person understand and appreciate the oath obliging him (or her) to tell the truth? To place this factor in context with a factor that the Secretary cited (education), does Dr. Sladky’s graduation from Yale University affect his ability to speak honestly? The Secretary does not grapple with the tension between misleading testimony regarding qualifications and accurate testimony regarding other topics, such as the significance of medical articles. At best, the Secretary conceded that “Respondent does not dispute Dr. Sladky’s decision not to be forthcoming with the professional ramifications of his alcoholism raises legitimate concerns regarding his credibility.” *Id.* at 3. In this characterization, the Secretary skips past the Court’s strong admonishments.<sup>11</sup>

In contrast, Mr. Contreras’s post-remand submission describes Dr. Sladky’s misrepresentations. In his post-remand view, Mr. Contreras argues that “the only remedy is to disregard his entire testimony.” Pet’r’s Resp., filed July 21, 2014, at 5 (emphasis omitted). In support, Mr. Contreras cites *Raymo*, a case in which the chief special master refused to give weight to Dr. Sladky’s evidence.

While the Secretary can be faulted for not paying sufficient attention to Dr. Sladky’s misconduct, Mr. Contreras goes to the other extreme. In his view, the “only” penalty for an expert’s misrepresentations in qualifications is disregarding the testimony entirely. However, this absolute consequence is not required in all cases. Striking testimony from an expert who misrepresented his (or her) background may be an appropriate penalty in some cases, but it is not the singular

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<sup>11</sup> The Court commented “Dr. Sladky was not candid about the events chronicled here with either respondent’s counsel or the court. . . . Dr. Sladky’s curriculum vitae misrepresented the state of his medical licensure at all times relevant to this litigation.” *Contreras 4*, 116 Fed. Cl. at 476 (emphasis in original). “Thus, the expert report filed by Dr. Sladky in 2005 was supported by an inaccurate and misleading CV.” *Id.* at 477. “Here, Dr. Sladky’s inaccurate CV prevented the special master and petitioner from ascertaining the true nature of Dr. Sladky’s medical practice and credentials at the times he opined as an expert in this case.” *Id.* “Dr. Sladky’s testimony, like his CV, failed to fully represent the existing state of his credentials and the existing conditions of his medical practice.” *Id.* at 479. Dr. Sladky’s testimony about the nature of his practice “is misleading.” *Id.*

appropriate response. For example, in a case not involving Dr. Sladky, the Secretary's cross-examination revealed instances of an expert's "resume padding," yet the special master proceeded to analyze the substance of the expert's opinion. Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at \*14-15, \*52 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for rev. denied, 88 Fed. Cl. 706, 744 n.65 (2009). In addition, as discussed by the Court, in Roberts, the special master did not strike Dr. Sladky's testimony. Instead, the special master described Dr. Sladky's opinion as "questionable" and found the petitioners' experts more reliable and persuasive. Contreras 4, 116 Fed. Cl. at 481 (citing Roberts, 2013 WL 5314698, at \*9). Mr. Contreras does not present any reasoned basis for preferring the outcome in Raymo, rather than the outcome in Roberts.

## **B. Standards for Adjudication**

A survey of cases from other jurisdictions suggests that admitting evidence relating to an expert witness's failure to disclose problems with licensing tends to be a question for the trial judge to consider as a matter of discretion. See George L. Blum, Annotation, Propriety of questioning expert witness regarding specific incidents or allegations of professional conduct or professional negligence, 11 A.L.R. 5th 1 (1993). For example, appellate courts have held cross-examination about the expert's record before a disciplinary board to be improper. Foley v. Mad River Internal Med., No. 2006-311, 2007 WL 5313351 (Vt. 2007) (exclusion of evidence sustained as within trial court's discretion); Tormey v. Trout, 748 So.2d 303 (Fla. Dist. Ct. App. 1999) (finding admission of testimony to be harmless error); Poole v. Univ. of Chicago, 542 N.E.2d 746, 750-51 (Ill. App. Ct. 1989) (ordering new trial). Similarly, a district court acts within its discretion to exclude testimony about misrepresentations in qualifications about a doctor in a malpractice trial. White v. United States, 148 F.3d 787, 791-92 (7th Cir. 1998).

At the other end of a spectrum are cases in which courts have reasoned that experts who misrepresent their qualifications should not be permitted to testify at all. Hamilton v. Negi, No. 09-CV-0860, 2012 WL 1067857 (W.D. La. Mar. 15, 2012) (magistrate recommendation). A case that approved this result is In re Unisys Savings Plan Litig., 173 F.3d 145 (3d Cir. 1999).

In Unisys, the plaintiffs alleged that their employer breached its fiduciary duty as prescribed by the Employee Retirement Income Security Act of 1974. The case was tried to the district court, not to a jury. The district court excluded the testimony of the plaintiff's proposed expert for three reasons, one of which was the expert had testified untruthfully about his credentials during voir dire. Id. at 156.



The three-judge panel of the Third Circuit split in its review of the decision to exclude the plaintiff's witness.

The majority of the panel affirmed the district court's decision to exclude the testimony as within the trial court's discretion. The majority reasoned that the fact that the district court was acting as both the gatekeeper who admits expert testimony and the finder of fact which weighs expert testimony was significant. Once the district court judge found that he could not find the expert's testimony credible, the judge was not required to hear "the witness's direct examination, cross-examination, and rebuttal examination in an extended trial when [the judge] knew that he would only reject it as unbelievable." Id. at 157.

Chief Judge Becker dissented from the ruling regarding the admissibility of the expert's testimony. Chief Judge Becker distinguished two aspects of reliability. In his view, the reliability of an expert's opinion under Daubert concerns the expert's methodology. "Credibility plays no appropriate part in the analysis of the reliability of a proposed expert's methodology." Unisys, 173 F.3d at 166 (citing Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993)). Because, according to the dissent, the expert's methodology was otherwise appropriate, the district court should have admitted the testimony. Chief Judge Becker asserted "that there is a reasonable chance that, if the District Court had given [the expert] the opportunity to present his testimony in full, it would have found him to be a credible witness." Id. at 173.

As noted, Chief Judge Becker's Unisys opinion was a dissent. However, in the next year, he wrote for a unanimous panel that reviewed a district court's decision to admit expert testimony in a case tried to a jury. Elcock v. Kmart Corp., 233 F.3d 734 (3d Cir. 2000). The Third Circuit held that the district court erred in admitting the expert's testimony without conducting a Daubert hearing to address the reliability of the expert's testimony because of concerns about the expert's methodology. As guidance for the remand, the Third Circuit also discussed whether the expert's dishonesty should affect the reliability inquiry. (The expert had pleaded guilty to embezzlement and knowing conversion of federal property.) The Third Circuit held "in reaching our conclusion about the reliability of [the expert's] methods, we do not consider evidence regarding [the expert's] credibility, or his alleged character for untruthfulness." Id. at 750. The Third Circuit declined to follow the outcome of Unisys because, in part, the finder of fact in Elcock was a jury, not a judge. Id. at 751. The District Court retained discretion to limit the cross-examination about the details about the expert's acts of dishonesty in front of the jury.

The approach taken in Elcock has been used frequently. In several cases, the trial court has permitted the expert to testify, has allowed the opposing side to cross-examine the expert about the professional misconduct (and the failure to disclose the misconduct), and expected that the finder of fact might consider the misconduct. See, e.g., Pikas v. Williams Companies, Inc., No. 8-CV-101, 2013 WL 622234 (N.D. Okla. 2013) (despite actuary's misrepresentation in his qualifications, his declarations would be considered); In re Heparin Prod. Liab. Litig., 803 F.Supp. 2d 712, 752 (N.D. Ohio 2011) (an expert who misrepresented his qualifications would not be excluded but the jury would be instructed that it may give his opinions greater scrutiny), aff'd sub nom. Rodrigues v. Baxter Healthcare Corp., 567 F. App'x 359 (6th Cir. 2014); Fitzpatrick v. Teleflex, Inc., 763 F.Supp. 2d 224, 236 (D. Me. 2011) (finding that the proffered person remains an expert in accounting despite having his CPA license revoked and stating that if the expert "testifies the factfinders will be allowed to hear about [his] difficulties with the licensing authority and that in spite of his license being suspended, he described himself as a CPA. A factfinder might well decide to give his opinion little weight in light of his professional difficulties, or not"). On appeal, this approach has been recognized as within the trial court's discretion. Creighton v. Thompson, 639 N.E.2d 234, 239-40 (Ill. App. Ct. 1994) (distinguishing Poole). Notably, even the majority of the Third Circuit in Unisys recognized that "appellate decisions affirming the trial court [regarding the qualifications of an expert witness] do not necessarily stand for the proposition that the opposite ruling would constitute error." In re Unisys, 173 F.3d at 157 n.17 (quoting Hanson v. Baker, 534 A.2d 665, 667 (Me. 1987)).

Here, the Remand Decision attempted to follow the course for which Chief Judge Becker advocated. Because Mr. Contreras had not filed a motion to strike Dr. Sladky's evidence and merely argued that this evidence receive greater scrutiny, an explicit assessment about the admissibility of his testimony seemed unnecessary. Therefore, the Remand Decision weighed the evidence coming from Dr. Sladky. See 42 U.S.C. § 300aa—13 (directing special master to make decision upon the entire record).

After the second remand, the status of Dr. Sladky's evidence has changed in two respects. First, the Court independently investigated Dr. Sladky's disclosures in other Vaccine Program cases, including Crosby v. Sec'y of Health & Human Servs., No. 07-799V, 2012 WL 3758430 (Fed. Cl. Spec. Mstr. June 19, 2012).

Contreras 4, 116 Fed. Cl. at 478.<sup>12</sup> Second, Mr. Contreras has now argued for the striking of Dr. Sladky's evidence. Pet'r's Resp., filed July 21, 2014, at 1.

The Court's instructions included a direction that "the special master must address Dr. Sladky's credibility and reliability in light of the consistent pattern of misrepresentations by Dr. Sladky in his work as an expert for respondent and provide an unambiguous estimation of Dr. Sladky's credibility and reliability as an expert." Contreras 4, 116 Fed. Cl. at 484. The Court appears to have adopted, implicitly, the views of the trial court and panel-majority from Unisys --- some expert witnesses may be so untruthful that they cannot be trusted in any respect. Nonetheless, the Court recognized that the initial evaluation of the expert's credibility and reliability is for the special master. Id. at 484 (citing Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005)).

### **C. Assessments**

The Court has ordered evaluations of two aspects of Dr. Sladky, his credibility and his reliability. The following sections attempts to respond to the Court's instructions regarding credibility and reliability.

#### **1. Credibility**

As suggested earlier, the parties' briefs concerning the standards by which to evaluate an expert's credibility were not particularly helpful. The Secretary's brief tended to focus on factors that contribute to the expert's reliability and persuasiveness, while ignoring the factors that concern truthfulness. Mr. Contreras, in turn, seemed to assume that once Dr. Sladky's pattern of misconduct was revealed, the sanction of striking his testimony would follow as a matter of rote.

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<sup>12</sup> Coincidentally, one issue in Crosby resembles an issue Mr. Contreras's case. As a preliminary matter, the special master determined that the vaccinee (a child) started to experience symptoms of transverse myelitis one day after vaccination. Crosby, 2012 WL 3758430, at \*5. The ensuing question, which matches a question in the case at hand, was whether 24 hours was a sufficient amount of time for the vaccine to have caused transverse myelitis. Based upon the evidence presented, the special master found "that 96 hours was the minimum amount of time necessary for an adaptive immune response, which is the type of immune response petitioner alleged caused the [transverse myelitis]. This evidence was agreed to by petitioner's own immunologist ... [who] specifically testified that onset within 24 hours would not be an appropriate time frame." Id.

Neither party identified any Federal Circuit decisions addressing how a trial court should respond to the revelation that an expert misrepresented his qualifications. Independent research also has not discovered any Federal Circuit cases. On the topic of the credibility of expert witnesses more generally, the Federal Circuit has given limited, and arguably inconsistent, guidance.<sup>13</sup> The Federal Circuit has explicitly recognized that a “finder of fact has to make the effort to decide which side has the stronger case. This can be based on the demeanor of the witnesses (if so, the trial judge should say) or the intellectual strength of the evidence based thereon.” Andrew Corp. v. Gabriel Elec., Inc., 847 F.2d 819, 824 (Fed. Cir. 1988) (quoting United States v. Gen. Motors Corp., 561 F.2d 923, 933 (D.C. Cir. 1977)).

In a trial before the court, the right of a judge to weigh the expert’s credibility was implicitly recognized in Energy Capital Corp. v. United States, 302 F.3d 1314 (Fed. Cir. 2002). The Federal Circuit stated: “As for the relative weight given to both sides’ expert witnesses, we accord the trial court broad discretion in determining credibility because the court saw the witnesses and heard the testimony.” Id. at 1329.

Consistent with those cases, which concerned judges as finders of fact, the Federal Circuit has accepted a special master’s reliance upon an expert’s credibility. The Federal Circuit commented:

Summarizing his assessment of the experts’ testimony on the issue of causation, the special master credited Dr. Snyder's evidence, but found the testimony given by Dr. Conkling and Dr. Lewis “unpersuasive.” Those findings, which are at the core of the special master's decision in this case, are largely based on his assessments of the credibility of the witnesses and the relative

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<sup>13</sup> Some of the inconsistency may stem from imprecision in the term “credibility.” See Isaac v. Sec’y of Health & Human Servs., No. 08-601V, 2012 WL 3609993, at \*19 (Fed. Cl. Spec. Mstr. July 30, 2012) (stating “[w]hat is meant by credibility in the Vaccine Program is not coextensive with the concept of reliability as applied to fact witnesses in a conventional trial setting. In the Vaccine Program, the concept is closer to reliability than believability”) (footnote omitted), mot. for rev. denied, 108 Fed. Cl. 743, aff’d without op., 540 Fed. Appx. 999 (Fed. Cir. 2013); cf. Haebe v. Dep’t of Justice, 288 F.3d 1288, 1300 (Fed. Cir. 2002) (noting imprecision in the use of “deference” as it relates to “concepts of credibility and demeanor”).

persuasiveness of the competing medical theories of the case.

Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1361-62 (Fed. Cir. 2000) (affirming a judgment denying compensation because the special master's determinations are "virtually unchallengeable on appeal").

But, the Federal Circuit's resolution of Lampe included a dissenting opinion from Judge Plager. Although acknowledging that "evaluations of credibility are 'virtually unreviewable,'" the dissent asserted that "credibility is not really the issue in this case." Id. at 1373 (Plager, J., dissenting) (citation omitted). The dissent proposed that the special master's finding that petitioner's experts were not persuasive was arbitrary and capricious. Id. at 1374 ("my quarrel is with the special master's evaluation of the evidence").

The Federal Circuit again discussed an expert's credibility in a 2009 case originating in the Vaccine Program. In that case, the special master found that petitioners were not entitled to compensation for three reasons: "(A) conflicts between [the child's] clinical presentation and Dr. Tornatore's [(the petitioners' expert)] theory; (B) the weight of the medical research showing no connection between DPT and afebrile seizures; and (C) my assessment of witness credibility." Andreu v. Sec'y of Health & Human Servs., No. 98-817V, 2008 WL 2517179, at \*5 (Fed. Cl. Spec. Mstr. May 29, 2008). When the case reached the Federal Circuit, it stated, "[t]he special master framed her rejection of [petitioners' expert's] theory of causation under the rubric of a 'credibility' determination." Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir 2009).

The Federal Circuit held that this was an error because special masters may not disguise an "erroneous legal standard" as a "credibility determination" regarding an expert witness. Id. The dissent from Lampe was the sole authority cited in support for the conclusion that a "trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence." Andreu, 569 F.3d at 1379. After identifying this error, the Federal Circuit reviewed the evidence, found "the totality of the evidence . . . sufficient to meet the Vaccine Act's preponderant evidence standard," and ruled the petitioners were entitled to compensation, reversing the Court's judgment, based upon the special master's dismissal. Id. at 1382.

The Federal Circuit's reversal in Andreu led to a conclusion that special masters should not consider an expert's credibility. See Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71, 80-81 (2009), rev'd on this ground sub nom. Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242 (Fed. Cir. 2011). But, interpreting Andreu to mean that special masters may never consider an expert's credibility was held to be too extreme. The Federal Circuit explained:

[T]he Claims Court read Andreu to mean that it is inappropriate for a special master to consider a petitioner's expert's credibility in evaluating a petitioner's showing of causation in fact.

The Claims Court's reading of Andreu is incorrect. Indeed, this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.

Porter, 663 F.3d at 1250. In this context, the Federal Circuit discussed opinions issued after Andreu, including Moberly, 592 F.3d at 1325, and Broekelschen, 618 F.3d at 1347. Porter, 663 F.3d at 1250 (citing Andreu, 569 F.3d at 1379; Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010); and Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010)).

Nevertheless, after Moberly and Porter, special masters rarely comment directly on an expert's credibility (in the sense of truthfulness) for several reasons. First, special masters may be faulted, after Andreu, of using credibility to escape appellate review. Second, the experts usually appear to be speaking honestly. Although the experts have differences in opinions and reach different conclusions, those disagreements frequently appear to be caused by differences in backgrounds and philosophies. In these circumstances, there is little to be gained by stating that each expert testified truthfully. Third, special masters generally respect the experts and appreciate their willingness to participate in the Vaccine Program. This gratitude typically extends even to those experts whom special masters do not find persuasive. Thus, special masters are often reluctant to criticize an expert on a personal level, such as by saying the expert appeared to be lying or misleading. But, when the special master needs to tell it like it is, the special master will describe instances of dishonest conduct. See King v. Sec'y of Health & Human Servs., 03-584V, 2011 WL 5926126, at \*12 (Fed. Cl. Spec. Mstr. Sept. 22, 2011)

(citing cases involving Dr. Mark Geier); Baker v. Sec'y of Health & Human Servs., No. 99-653V, 2003 WL 22416622, at \*33-36 (Fed. Cl. Spec. Mstr. Sept. 26, 2003) (Dr. John Barthelow Classen), mot. for rev. denied, 61 Fed. Cl. 669 (2004), appeal dismissed, 112 Fed. Appx. 35 (Fed. Cir. 2004); Mahaffey v. Sec'y of Health & Human Servs., No. 01-392V, 2003 WL 22424989, at \*12 (Fed. Cl. Spec. Mstr. May 30, 2003), aff'd on other grounds, 368 F.3d 1378 (Fed. Cir. 2004).

The revelation that Dr. Sladky was not forthright in disclosing his Georgia licensing problems places Mr. Contreras's case among the minority of cases in which the expert's credibility (again, in the sense of truthfulness) is a factor. A list of factors to consider in evaluating whether a person speaks credibly (or honestly) is based upon jury instructions. These factors include: "(1) the witness's demeanor; (2) the witness's motives, biases, interests, and prejudices; (3) whether the witness is contradicted by prior inconsistent statements or by other evidence; (4) the reasonableness of the witness's testimony, in light of other evidence; and (5) any other factors that bear on believability." Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at \*43 n.136 (Fed. Cl. Spec. Mstr. May 29, 2009), mot. for rev. denied, 91 Fed. Cl. 126 (2010). This list of factors to consider in evaluating the credibility of an expert witness from Hennessey is very similar to the Merit System Protection Board's list of factors to consider in evaluating the credibility of a percipient witness. The MSPB's factors are

- (1) The witness's opportunity and capacity to observe the event or act in question; (2) the witness's character; (3) any prior inconsistent statement by the witness; (4) a witness's bias, or lack of bias; (5) the contradiction of the witness's version of events by other evidence or its consistency with other evidence; (6) the inherent improbability of the witness's version of events; and (7) the witness's demeanor.

Hillen v. Dep't of the Army, 35 M.S.P.R. 453, 458 (1987), quoted in Haebe, 288 F.3d at 1301 n.30. By these standards, Dr. Sladky was credible at times and not credible at other times.<sup>14</sup>

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<sup>14</sup> To be more precise, "credibility" in this context is roughly synonymous with honesty. "Credibility" also has a measure of accuracy, attention to detail, forthrightness, and impartiality.

The evidence has revealed four instances where Dr. Sladky was not truthful and all relate to his background. Presented in chronological order, beginning with the earliest, these events occurred as follows. First, Dr. Sladky did not change his CV to note that his license to practice medicine in Pennsylvania had expired although Dr. Sladky changed his CV in other respects. Second, Dr. Sladky's alcoholism led to issues at the Georgia State Medical Board.<sup>15</sup> Third, Dr. Sladky failed to disclose the loss and restriction of his license. Fourth, Dr. Sladky testified misleadingly about the nature of his practice.

This list also roughly corresponds to the degree of severity. Dr. Sladky's alcoholism does not, by itself, reduce Dr. Sladky's credibility. The issues that underlie Dr. Sladky's alcoholism are not necessarily the same as an inability or an unwillingness to speak truthfully. See Settle v. Basinger, No. 11CV1342, 2013 COA 18, ¶ 81-86, 2013 WL 781110, at \*11-12 (Colo. App. Feb. 28, 2013), cert. denied, 2013 WL 6804561 (Colo. 2013); State v. Porter, 738 A.2d 1271, 1274 (N.H. 1999). The problem, however, is that Dr. Sladky did not disclose how his alcoholism affected his medical license.

The lack of disclosure (the third event) more significantly reduces Dr. Sladky's credibility than the mistake in Dr. Sladky's CV (the first event). Dr. Sladky should have indicated that his license to practice medicine in Pennsylvania expired. His failure to show the correct status of his license was an error. But, the error still appears to be an oversight, not an intentional effort to mislead the parties, the undersigned, or the Court. The basis for this conclusion is that Dr. Sladky would be unlikely to believe that the Secretary or he would gain any advantage in litigation because he was licensed to practice medicine in two states (Pennsylvania and Georgia), rather than one state (Georgia). The Court found that Dr. Sladky did not correct the status of his Pennsylvania license in his CV submitted in other cases, despite updates in other respects. Contreras 4, 116 Fed. Cl. at 478. This is true. Nevertheless, this pattern does not show an intent to deceive. The pattern is consistent with an oversight that remains unnoticed (and, therefore, uncorrected).<sup>16</sup> If Dr. Sladky's only fault were a misstatement about his licensure status in one jurisdiction, he would be found credible to testify.

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<sup>15</sup> A sequence of events took place before the Georgia Board: a voluntary relinquishment of Dr. Sladky's license for a time, a suspension of his license, and the restoration of the license with conditions. All these problems seem to flow from his alcoholism.

<sup>16</sup> If an error in an expert's CV were called to the expert's attention and the expert did not correct the error, the inference of intent to deceive could be found more readily.



However, as discussed at length, Dr. Sladky's mistakes did not end with the expired Pennsylvania license. He also failed to disclose that his Georgia license was voluntarily relinquished, suspended, and restored on a probationary basis. District courts, usually in the context of cases being tried to a jury, have not always excluded the expert's testimony due to misrepresentations in the proposed expert's qualifications. Instead, the district court has admitted the testimony, allowed cross-examination, and left the finder of fact to weigh the expert's testimony. White, 148 F.3d at 791-92 (finding doctor's credibility was a collateral issue); Fitzpatrick, 763 F.Supp. 2d at 236 (finding expert remained qualified due to experience); Pikas, 2013 WL 622234, at \*2 (court considered declaration of actuary when it ruled on damages issues).

Unlike the situation regarding the Pennsylvania license, Dr. Sladky's lack of disclosure for Georgia problems appears to be intentional. Dr. Sladky could easily have understood that a doctor's experience in treating patients may affect how a special master evaluates testimony from that doctor. For example, a neurologist with 15 years of experience may be more readily accepted than a neurologist with only 5 years of experience. In not being forthcoming about his licensing issues in Georgia, Dr. Sladky was implicitly representing himself as a doctor with experience in neurology since at least 1983, when he received his board certification. See exhibit J (CV) at 3. However, as the Court calculated, he could not practice medicine for 15 and a half months. Contreras 4, 116 Fed. Cl. at 479. Thus, he did not really have the experience he claimed.

In addition, the loss of his license leads to questions about why it was lost. If the Georgia State Medical Board suspended Dr. Sladky's license due to errors in treating patients, then this disciplinary action would undermine Dr. Sladky's medical knowledge. It is relatively easy to find that Dr. Sladky feared answering questions about why he lost his license and his fear motivated him to do what he could to avoid answering those questions. What Dr. Sladky did to protect himself was to remain silent. This was an error on Dr. Sladky's part and this error appears to be intentional.

The final factor weighing against Dr. Sladky's credibility was his testimony regarding his practice. He, again, did not disclose his Georgia licensure problems. The Court found "Dr. Sladky's testimony was misleading as to his experience and qualifications to testify as an expert." Contreras 4, 116 Fed. Cl. at 479.

On the basis of these four factors, the chief special master in Raymo found that Dr. Sladky "demonstrated a lack of candor that, although not related directly to

the substance of [his] causation opinions, reflect[s] [a] willingness to, at the very least, shade the truth.” Raymo, 2014 WL 1092274, at \*16. Thus, the chief special master in Raymo found that Dr. Sladky’s testimony should not be credited in any respect and did not further analyze the substance of his testimony.

Given that Dr. Sladky testified in Mr. Contreras’s case, it is appropriate to review the remainder of his testimony to look for places when he could be viewed, in the words of the chief special master in Raymo, as shading the truth. See In re Unisys, 173 F.3d at 173 (Becker, C.J., dissenting) (“there is a reasonable chance that, if the District Court had given [the expert] the opportunity to present his testimony in full, it would have found him to be a credible witness”). The remainder of Dr. Sladky’s testimony should be considered in evaluating his credibility because special masters should consider the entire record in making a decision. 42 U.S.C. § 300aa—13.

Does Dr. Sladky’s substantive testimony demonstrate other examples of presenting something other than the truth, the whole truth, and nothing but the truth? Apart from the aspect of his testimony concerning his personal qualifications, Dr. Sladky appeared accurate, honest, and forthcoming. Dr. Sladky was accurate, for instance, in 2005, when he cited the 1994 IOM report for the proposition this group of scientists found that the minimum amount of time for an immune-mediated response is 5 days. Exhibit I at 3. The IOM actually does assert “a conservative estimate of the limits of the latencies for both GBS and ADEM is conserved to be from 5 days to 6 weeks.” Exhibit F at 45. Dr. Sladky’s reliance on the 1994 IOM report does not appear to constitute an attempt to mislead the special master or to shade the truth.

Moreover, Dr. Sladky was forthcoming in his substantive opinion. He was not adverse to everything Mr. Contreras asserted. For example, Dr. Sladky conceded that he did not identify any factor that could have caused Mr. Contreras’s transverse myelitis. Tr. 299, 351. Dr. Sladky maintained that Mr. Contreras’s previous exposure to the Epstein Barr virus did not make Mr. Contreras vulnerable to developing transverse myelitis. Tr. 301. These opinions helped Mr. Contreras because they negated the possibility of the Secretary mounting a defense based upon a factor unrelated to a vaccine caused the transverse myelitis.

More significantly, Dr. Sladky assisted Mr. Contreras regarding Mr. Contreras’s attempt to establish the first prong of Althen. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). In the context of considering whether a medical theory supported the claim that the hepatitis B

vaccine can cause transverse myelitis, Dr. Sladky was asked about the factors from Daubert. Dr. Sladky stated that he believed that a majority of neurologists would accept that vaccines can cause transverse myelitis. Tr. 386. The Remand Decision discussed this concession. Contreras 3, slip op. at 46, 2013 WL 6698382, at \*36.

For purposes of assessing Dr. Sladky's credibility or his willingness to shade the truth, it is important to recognize that Dr. Sladky was not compelled to opine that the theory that vaccines can cause transverse myelitis is generally accepted. He could have asserted that very few neurologists accepted this theory because there was no way to verify Dr. Sladky's assertion. This example demonstrates that Dr. Sladky was willing to be honest about information that was detrimental to the Secretary's position on one occasion. Cf. Tr. 395 (Dr. Sladky testified that he recommended that the Secretary compensate a petitioner in a case 12-13 years earlier).

For his substantive opinions, Dr. Sladky appeared credible. When asked on cross-examination whether he tried to be "fair and straightforward with the Court on what [he] saw and what [his] opinions are," Dr. Sladky responded affirmatively. Tr. 328. Notably, the Secretary queried whether Dr. Sladky interpreted a peer-review article incorrectly. Resp't's Resp., filed June 23, 2014, at 8. Yet, given this challenge, Mr. Contreras did not propose that Dr. Sladky misinterpreted an article. Mr. Contreras did not identify any instances in which Dr. Sladky arguably presented a shaded opinion in substance. See Pet'r's Resp., filed July 21, 2014; at 1-5.

On the whole, Dr. Sladky's candor on substantive matters offsets his lack of disclosures regarding personal matters. Dr. Sladky is sufficiently credible that his testimony should be evaluated for its reliability.

## 2. Reliability<sup>17</sup>

Within the Vaccine Program, the reliability of an expert's opinion is often analyzed using the Daubert factors. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 133 (2011), aff'd per curiam, 463 Fed. Appx. 932 (Fed. Cir. 2012). This evaluation is usually for petitioner's expert because the petitioner usually bears the burden of demonstrating the reliability of the opinion. The Daubert factors include:

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<sup>17</sup> The reliability of Dr. Sladky's opinion does not take into account the lack of disclosures that diminish his credibility.

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Daubert, 509 U.S. at 592-95. Assessing the reliability of the expert's opinion usually includes considering the expert's methodology. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1998) (citing Daubert, 509 U.S. at 595).

The Remand Decision analyzed all the evidence regarding the theory that the hepatitis B vaccine can cause transverse myelitis via molecular mimicry. Contreras 3, slip op. at 43-48, 2013 WL 6698382, at \*34-38. However, Contreras 3 did not separately evaluate Dr. Sladky's opinion. Because the Court has required an appraisal of Dr. Sladky's "reliability," this task is undertaken now with respect to Dr. Sladky's opinions regarding diagnosis, timing, and causation. See Contreras 4, 116 Fed. Cl. at 484.

**a) Diagnosis**

From October 2005 through the April 20, 2010 hearing, Dr. Sladky opined that Mr. Contreras suffered from transverse myelitis and only transverse myelitis. The aspect of Dr. Sladky's opinion that Mr. Contreras suffered from transverse myelitis was not contested. The second MRI showed a lesion in Mr. Contreras's spinal cord, indicating inflammation in his spinal cord. Exhibit 7 at 177, 1723. The consensus among the experts about transverse myelitis establishes the reliability of Dr. Sladky's opinion for transverse myelitis.

The aspect of Dr. Sladky's opinion that Mr. Contreras suffered from only transverse myelitis (and not Guillain-Barré syndrome) is disputed. During this litigation, Dr. Steinman and Dr. Poser revived Guillain-Barré syndrome. However, a mere disagreement among experts does not necessarily make one expert's opinion unreliable. The opinion could be reliable but not persuasive.

Here, Dr. Sladky followed an appropriate methodology in ruling out Guillain-Barré syndrome as a diagnosis for Mr. Contreras. See Tr. 281-93. Mr. Contreras did not present any persuasive evidence that Dr. Sladky deviated from general medical practice by, for instance, using an outdated set of diagnostic

criteria or ignoring test results.<sup>18</sup> Dr. Sladky's opinion regarding diagnosis is reliable.

### **b) Timing**

The next opinion from Dr. Sladky is an assertion that one day is not a sufficient amount of time for a vaccine to cause a demyelinating disease. Dr. Sladky expressed this opinion in his October 21, 2005 report (exhibit J at 4-5), in his March 4, 2010 supplemental report (exhibit O at 2), and in his testimony on cross-examination (Tr. 329).<sup>19</sup>

A substantial amount of evidence supports the reliability of Dr. Sladky's opinion. The most important article is the 1994 report from the Institute of Medicine (IOM). Exhibits A, F, and V. Cases from the Vaccine Program have cited the 1994 IOM report because of the expertise of the contributors to the IOM report and Congress directed the IOM to research the safety of vaccines as part of the Vaccine Program. See Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 91 n.11 (2005); Kuperus v. Sec'y of Health & Human Servs., No. 01-60V, 2003 WL 22912885, at \*10 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); White v. Sec'y of Health & Human Servs., No. 98-426V, 2002 WL 1488764, at \*6, \*11 (Fed. Cl. Spec. Mstr. May 10, 2002) (setting forth petitioner's arguments and accepting petitioner's argument regarding timing); Exhibit C (Institute of Medicine, Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders (Kathleen Stratton et al., eds. 2002)) at 2 (discussing congressional mandate for vaccine safety research).<sup>20</sup>

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<sup>18</sup> Dr. Sladky appears to have weighed results of some tests particularly the Babinski reflex differently than Dr. Steinman. But, assigning different weights to a test is not the same as ignoring the test.

<sup>19</sup> The Secretary, on direct examination, elicited a small amount of testimony from Dr. Sladky about the timing between vaccination and onset. Tr. 279-81, 310 (discussing rodent studies).

<sup>20</sup> For examples of appellate authorities endorsing a special master's reliance on reports from the IOM other than the 1994 report, see Porter, 663 F.3d at 1252-54 (2002 report); Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1529 (Fed. Cir. 1993) (1991 report); Isaac v. Sec'y of Health & Human Servs., 108 Fed. Cl. 743, 768-74 (2013), aff'd, 540 Fed. Appx. 999 (Fed. Cir. 2013) (2011 pre-publication report); Terran v. Sec'y of Health & Human Servs., 41 Fed. Cl. 330, 337 (1998) (1991 report and different 1994 report), aff'd, 195 F.3d 1302, 1317 (Fed. Cir. 1999).

The 1994 IOM report stated that an immune-mediated response leading to a demyelinating disease would take “5 days to 6 weeks.” Exhibit F at 45. The Secretary cited the 1994 IOM report in her October 7, 2005 Rule 4 Report and Dr. Sladky also cited it in his October 21, 2005 report. Exhibit J at 3.

Given the pedigree of the IOM report, Dr. Sladky’s reliance on it means that his opinion easily surpasses the minimum standards for reliability. A methodology of relying upon the work from a set of extremely well-qualified experts is sound. Mr. Contreras has not called into question the findings of the 1994 IOM panel by challenging their credibility or expertise.<sup>21</sup>

Other articles, although less prestigious than an IOM report, further buttress the reliability of Dr. Sladky’s opinion regarding latency. Two articles collected case reports of patients who developed neurological problems after vaccination. One stated “[a]cute transverse myelitis . . . begins three to 14 days after an antecedent immunization.” Exhibit 29 (L. Reik, Jr., Neurological complications of immunization, 2 *Neurology Infections & Epidemiology* 69, 75 (1997)) at 7. In the other case series, the minimum amount of time between vaccination and the onset of neurologic symptoms was four days. Exhibit 34 (A. Tourbah et al., Encephalitis after hepatitis B vaccination: Recurrent disseminated encephalitis or MS?, 53 *Neurology* 396 (1999)).

For his opinion regarding timing, Dr. Sladky easily meets the Daubert criteria for peer review and general acceptance. Thus, his opinion is reliable.

### **c) Causation**

A third opinion offered by Dr. Sladky was that the evidence did not support a finding that the hepatitis B vaccine can cause transverse myelitis. One reason was that the epidemiological studies, such as Touze, that investigated a possible connection between the hepatitis B vaccine and demyelinating diseases and found none. See exhibit I at 4 (citing exhibit E (E. Merelli & F. Casoni, Prognostic factors in multiple sclerosis: role of intercurrent infections and vaccinations against influenza and hepatitis B, 21 *Neurological Science* S853 (2000)); exhibit G (Emmanuel Touze et al., Hepatitis B Vaccination and First Central Nervous

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<sup>21</sup> In the context of cross-examining Dr. Whitton, who relied upon yet another IOM report, Mr. Contreras suggested that the IOM required scientific certainty. Tr. 464-66. However, Dr. Whitton understood that the standard for proof in the Vaccine Program is more likely than not. Tr. 500.

System Demyelinating Event: A Case-Control Study, 21 *Neuroepidemiology* 180 (2002)); and exhibit H (Frauke Zipp et al., No increase in demyelinating diseases after hepatitis B vaccination, 5(9) *Nature Medicine* 964 (1999)). In emphasizing the results of epidemiologic studies, Dr. Sladky downplayed the significance of case reports. Tr. 295-97.

This methodology is reliable, both from a medical perspective and a legal perspective. As discussed in the Remand Decision, Dr. Chen from the Centers of Disease Control stated “[i]n the hierarchy of weight of scientific evidence, data from well-designed randomized clinical trials clearly outweighs that from well-controlled observational studies, which in turn, is hierarchically better than uncontrolled observational studies, case series, and then finally, case reports.” Exhibit 15 (Robert T. Chen et al., Epidemiology of Autoimmune Reactions Induced by Vaccination, 16 *Journal of Autoimmunity* 309, 312 (2001)) at 4. Similarly, the 2002 IOM panel placed little weight on case reports, commenting “[c]ase reports are useful for describing the domain of concerns, but the data are usually uncorroborated clinical descriptions that are insufficient to permit meaningful comment or to contribute to a causality argument.” Exhibit C (2002 IOM) at 39. In addition, the Federal Judicial Center has published guidance to judges, indicating that case reports are usually not sufficient to show causation. David H. Kaye & David A. Freedman, Reference Guide on Statistics, in *Reference Manual on Scientific Evidence* 211, 218 (Federal Judicial Center, 3d ed. 2011). Thus, Dr. Sladky, in reaching his conclusion that the evidence does not show that hepatitis B vaccine causes demyelinating diseases, followed an appropriate methodology.<sup>22</sup>

### Overall

Dr. Sladky satisfies the minimal standard for credibility. Dr. Sladky also offered opinions based upon reliable methodologies. His opinions, therefore, remain in the record and, to the extent that Mr. Contreras has argued that his testimony should be stricken, Mr. Contreras’s request is denied.

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<sup>22</sup> Dr. Sladky’s methodology is appropriate for a doctor. The standards for this profession differ from the standards special masters use in adjudicating claims. In the Vaccine Program, a petitioner is not required to submit epidemiological studies, but when those studies are submitted, the special master may consider them. Andreu, 569 F.3d at 1379.

### III. Comparisons

The Court directed a second determination: “the special master must compare Dr. Sladky’s credibility to the credibility of the experts for the petitioner and the witnesses testifying for petitioner.” Contreras 4, 116 Fed. Cl. at 484. The standards for reviewing an expert’s credibility were set forth in the preceding section. See section II.B. The relevant factors include the testifying witness’s demeanor. See Bailey v. United States, 54 Fed. Cl. 459, 461-63 (2002) (citing cases), aff’d, 94 Fed. Appx. 828 (Fed. Cir. 2004). In accord with the Court’s instructions, the following is an assessment of credibility listed from the least credible to the most credible.

**Dr. Wagner:** Dr. Wagner’s background indicates that he is knowledgeable about emergency room medicine and the records created on June 17, 2003, show that he used his skills to stabilize Mr. Contreras. Exhibit 13 (CV) at 13-19; exhibit 6 (medical records). His testimony about how he cared for Mr. Contreras largely tracked the records from that time. Tr. 67-90. His testimony about Mr. Contreras’s signs and symptoms and Dr. Wagner’s response to those signs and symptoms was believable. There is no doubt that Dr. Wagner sincerely thought that transverse myelitis, Guillain-Barré syndrome, and other diseases were potentially affecting Mr. Contreras.

Dr. Wagner’s differential diagnosis, although honest, is not worth as much as the more definitive conclusion reached by Mr. Contreras’s treating neurologist, Dr. Lake, that Mr. Contreras suffered from transverse myelitis and not Guillain-Barré syndrome. Dr. Wagner’s opinion regarding diagnosis is discounted for two reasons, neither of which implicates his credibility. First, Dr. Wagner saw Mr. Contreras for approximately five hours. Tr. 91; see exhibit 6 at 9 (showing examination time as 12:20); Tr. 67 (same); exhibit 6 at 5 (showing discharge time as 4:59 P.M.). During this five-hour period, Mr. Contreras underwent one MRI. However, after Mr. Contreras left Dr. Wagner’s hospital for a facility that provided a higher level of care, Mr. Contreras had another MRI. See Tr. 89. This second MRI, which Dr. Wagner never reviewed, was the basis for Dr. Lake’s conclusion that Mr. Contreras suffered from transverse myelitis. See Tr. 84 (Dr. Wagner acknowledging that an early MRI may not show transverse myelitis). The second reason for crediting Dr. Lake’s opinion over Dr. Wagner’s opinion is that Dr. Lake is a neurologist. She specializes in diseases that affect the nervous system, such as transverse myelitis and Guillain-Barré syndrome. Thus, she had better information about Mr. Contreras and is better qualified to interpret that information.



Although Dr. Wagner was credible but not persuasive in opining about Mr. Contreras's diagnosis, his opinion regarding etiology was much less credible. Dr. Wagner is not a specialist in immunology or neurology, the two specialties most relevant to Mr. Contreras's claim. Tr. 90. In addition, Dr. Wagner displayed a prejudice in favoring a claim that vaccines can cause harm. Dr. Wagner appeared angry that a vaccine, given to him in the 1970's, harmed him. Tr. 93.

In addition, as noted in the Entitlement Decision, Dr. Wagner informed his opinion that the hepatitis B vaccine harmed Mr. Contreras based on a review of only the reports of Drs. Garrett and Steinman, and not those of Drs. Sladky or Whitton. Contreras 1, 2012 WL 1441315, at \* 22 (citing Tr. 97-98). This selective review suggests that Dr. Wagner formed an opinion about causation and then looked for support for that opinion. He did not consider an opposing viewpoint. This lack of neutrality made Dr. Wagner appear to be more of an advocate than an expert who sees his role as being one to help the finder of fact make informed decisions. Special masters have given biased testimony from experts less weight. Brousard-Pacot v. Sec'y of Health & Human Servs., No. 09-107V, 2012 WL 5357478, at \*13 (Fed. Cl. Spec. Mstr. Sept. 4, 2012) (rejecting testimony of expert who "reasoned backwards"); Isaac, 2012 WL 3609993, at \*23 n.37 ("[t]o the extent that [petitioner's expert's] opinion appears to be that of a partisan rather than an objective expert, his opinion carries less weight"); Hopkins v. Sec'y of Health & Human Servs., No. 00-746V, 2007 WL 5403504, at \*6 (Fed. Cl. Spec. Mstr. Dec. 14, 2007) (citing position statement of American Academy of Emergency Medicine that a member must "impartially assist the Court"), mot. for rev. denied, 84 Fed. Cl. 517 (2008).

This bias about the issues in Mr. Contreras's case makes Dr. Wagner a witness with less credibility than Dr. Sladky. Although Dr. Sladky was misleading about his background, Dr. Sladky testified accurately about the issues in Mr. Contreras's case. Accurate testimony about the issues in the case is more important to me than accurate testimony about a person's background. Although other finders of fact could reasonably weigh these factors differently, my sense is that Dr. Wagner is less credible than Dr. Sladky.

**Dr. Sladky:** The next witness in terms of credibility is Dr. Sladky. He was deceptive with respect to his background but forthright on issues involving Mr. Contreras.

**Dr. Steinman**: Dr. Steinman's credibility has not been called into question in the way that Dr. Sladky's credibility has been diminished. There has been no argument that he was deceptive or misleading about his background.

Nonetheless, there are concerns about his credibility. Dr. Steinman's demeanor suggests that he saw his role as advocate for the party retaining him and he, at times, used language to elicit an emotional response to favor Mr. Contreras. Tr. 116, 155, 221 ("I'm trying to argue as strongly as I can"), 256, 262 ("I choose to look at that part of the story to strengthen the case here for the Petitioner"), 535. His interpretation of some articles seemed far-fetched and evidenced a willingness to stretch to find some material to support his position.<sup>23</sup> See Tr. 218-22. He was not always precise in recounting what an experiment showed. See Tr. 243-49 (discussing exhibit 118 (Odoardi)).

Dr. Steinman also was inconsistent at times. Within Mr. Contreras's case, Dr. Steinman's opinion about race and ethnicity seemed to fluctuate, depending upon whether the result helped or hurt Mr. Contreras. Dr. Steinman argued that epidemiological studies like Zipp (exhibit H) and Touze (exhibit G), which made a causal connection between vaccinations and neurologic disease less likely, could not be applied to Mr. Contreras because of his Hispanic ancestry. Tr. 192. Yet, Dr. Steinman drew upon case reports of injuries occurring after vaccination in non-Hispanic people as well as the Bogdanos study (exhibit 61) that also did not involve Hispanics. Tr. 193-95, 256 (discussing Dimitrios-Petrou Bogdanos et al., A study of molecular mimicry and immunological cross-reactivity between hepatitis B surface antigen and myelin mimics, 12(3) Clinical & Developmental Immunology 217 (2005)). This inconsistent treatment diminishes Dr. Steinman's credibility to some degree.<sup>24</sup>

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<sup>23</sup> Another special master made a similar appraisal of Dr. Steinman's approach to litigation. See Mueller v. Sec'y of Health & Human Servs., No. 06-775V, 2011 WL 1467938, at \*19 n.19 (Fed. Cl. Spec. Mstr. Mar. 16, 2011) ("advocating a position is not credible").

<sup>24</sup> While the example of racial background occurred solely within Mr. Contreras's case, Dr. Steinman appears to have offered an opinion in Mr. Contreras's case that is inconsistent with opinions Dr. Steinman offered in other cases. Whether evidence from other cases may be a factor in determining an expert's credibility is unclear. The Court stated that "a special master should not base his findings on causation-in-fact in one case on other Vaccine Act cases." Contreras 2, 107 Fed. Cl. at 308. The Court also considered Dr. Sladky's CV in Crosby. Contreras 4, 116 Fed. Cl. at 478.

(continued...)

**Dr. Poser:** Dr. Poser submitted two affidavits and did not testify in person. Thus, there was no opportunity to assess his demeanor.

There is no evidence to suggest that Dr. Poser was deceptive about his background or made assertions in his affidavits that he knew were untruthful. In that sense, Dr. Poser was credible.

On the other hand, Dr. Poser's affidavits present generalities. For example, although Dr. Poser recognized that the minimum time for an immune-mediated reaction is usually five days, Dr. Poser also asserted that there would always be people who react differently from the masses. Exhibit 23 at 3-4, ¶ 6. Dr. Poser did not explain why an "outlier" could react in only one day. The lack of explicit reasoning from Dr. Poser calls into question the reliability of his assertion. This determination probably is better characterized as a lack of persuasiveness (as opposed to a lack of credibility).

**Dr. Garrett:** Dr. Garrett, like Dr. Poser, testified by affidavit. Since he did not appear in person, there was no opportunity to observe his demeanor.

Dr. Garrett appeared credible in his role as a treating doctor. When caring for Mr. Contreras, he deferred to Dr. Lake's opinion on diagnosis. Exhibit 7 at 136. He also refrained from speculating about the cause of Mr. Contreras's transverse myelitis when counseling Mr. Contreras's parents. *Id.* at 147.

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If outside evidence were an appropriate source for finding inconsistent opinions, then there would be more examples of Dr. Steinman's inconsistency. *Cf. Holmes v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 469, 490-91 (2014) (suggesting, but not deciding, that a special master may consider other cases' determination of an expert's reputation and credibility). In other cases, Dr. Steinman has asserted that the time for a vaccine to cause an injury via molecular mimicry is several days. *Dillon v. Sec'y of Health & Human Servs.*, No. 10-850V, 2013 WL 3745900, at \*9 (Fed. Cl. Spec. Mstr. June 25, 2013) (Dr. Steinman "observed that the medically accepted time frame for the onset of a post-vaccinal transverse myelitis would be a few weeks"); *Brown v. Sec'y of Health & Human Servs.*, No. 09-426V, 2011 WL 5029865, at \*21 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) ("Dr. Steinman accepts a causal interval of a week or two up to 10 weeks"); *Ricci v. Sec'y of Health & Human Servs.*, No. 99-524V, 2011 WL 2260391, at \*12 (Fed. Cl. Spec. Mstr. May 16, 2011) (quoting Dr. Steinman as testifying that the process of molecular mimicry can damage a part of the brain and cause a seizure "within a week. A lot short than that, we could have problems making the argument"), *mot. for rev. denied*, 101 Fed. Cl. 385 (2011). When the Secretary asked about at least one of these instances on cross-examination, Dr. Steinman requested an opportunity to review the transcript from his earlier testimony. Tr. 202.

In this litigation, Dr. Garrett opined that the hepatitis B vaccine caused Mr. Contreras's transverse myelitis. Dr. Garrett did not explain the reasoning for a change in his views regarding etiology from first not knowing the cause, to then identifying the vaccine as a cause. This lack of explanation undercuts Dr. Garrett's opinion. The Court has previously recognized that a special master may give less weight to the statement of a treating doctor that is presented in the context of litigation, especially when the treater's statement "is devoid of any supporting evidence." Ruiz v. Sec'y of Health & Human Servs., No. 02-156V, 2007 WL 5161754, at \*15 (Fed. Cl. Oct. 15, 2007).

Like Dr. Poser, Dr. Garrett's conclusion that one day is an appropriate temporal interval was not persuasive. He appeared to use a methodology in which he looked for examples (case reports) of demyelinating diseases that appeared after vaccination. The problem, as discussed in the Remand Decision, is that none of the case reports Dr. Garrett cites shows such a quick onset. Contreras 3, slip op. at 52, 2013 WL 6698382, at \*41. The lack of corroboration from the material that Dr. Garrett cited makes his opinion less persuasive, and maybe less credible.

**Dr. Kyazze:** Dr. Kyazze appeared credible. He testified in accord with the examination he conducted of Mr. Contreras on June 16, 2003. Exhibit 4 at 25; Tr. 43-52, 59-61 (indicating that Dr. Kyazze reviewed his records before testifying).

Dr. Kyazze appeared to care that what he was saying was accurate. For example, he stated that although some infections cause an increase in white blood cells, not all infections do. Tr. 53.

Similarly, he was not willing to exceed the basis of his knowledge. He would not say that the vaccinations caused the transverse myelitis because he did not know that assertion to be accurate. Tr. 56.

Overall, Dr. Kyazze was a believable doctor. He testified about what he knew and refrained from testifying about what he did not know.

**Dr. Whitton:** Of all the testifying doctors, the most credible witness was Dr. Whitton. His demeanor suggested that he undertook the role of an expert from the perspective of someone who was asked to present a report. See Tr. 473. Dr. Whitton, in contrast to Dr. Steinman, appeared interested in providing the most accurate information, not the information that would help "his side" prevail.

Dr. Whitton appeared to possess prudent judgment. For example, he declined the position of editor for one important journal because he was already

serving as an editor on another journal. Dr. Whitton did not want to hinder the dissemination of multiple viewpoints. Tr. 410. Although he relied upon epidemiological studies, he also appreciated that epidemiological studies are limited. Tr. 469.

Before concluding that one day was not a medically appropriate interval from which to infer causation, Dr. Whitton reviewed Dr. Steinman's reports and the articles cited in those reports with care. Dr. Whitton appeared to look to see if anything supported Dr. Steinman's views. See Tr. 434-38, 473. Dr. Whitton brought a positive tone to the hearings. See Tr. 435, 438 (complimenting the work of Dr. Steinman and colleagues at Stanford and calling Drs. Steinman and Poser "renowned" neurologists). This lack of bias contributed to Dr. Whitton's extremely high credibility.<sup>25</sup>

#### **IV. Adjudication after Excluding Dr. Sladky**

For the reasons explained in Section II, Dr. Sladky is sufficiently credible and sufficiently reliable that his evidence should remain in the record. Thus, the outcome of the Remand Decision, a denial of compensation, does not differ.

Nonetheless, the Court's third (and final) instruction was for the undersigned to make alternative findings of fact without any consideration of Dr. Sladky's evidence. This section complies with the Court's direction. The section begins with the standards for adjudication, which are brief because they have been set forth in earlier discussions and decisions in this case.

Next, there are four sections corresponding to four aspects of Mr. Contreras's case: diagnosis, timing, theory, and logical sequence. For each of these sections, the Remand Decision is summarized, highlighting the citations to Dr. Sladky's evidence. Then, the effect of excluding Dr. Sladky's evidence is described. The same result is reached because of the strength of the other evidence remaining in the case.

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<sup>25</sup> Another special master "found Dr. Whitton's testimony on the lack of evidence for molecular mimicry at work in humans after viral infection to be highly persuasive." Hennessey, 2009 WL 1709053, at \*53 n.156. Dr. Whitton "was an exceptionally good expert witness, one who made difficult immunologic concepts readily understandable. His thoughtful (and helpful) responses to questions both on cross-examination and from the court could serve as a model for what expert testimony should be, and unfortunately, so rarely is." Id. at \*11.

### **A. Standards for Adjudication**

The Court previously set forth the parties' respective burdens and the elements of compensation. Contreras 2, 107 Fed. Cl. at 291-92. Those statements are incorporated into this decision.

In brief, Mr. Contreras seeks compensation on the theory that he suffered Guillain-Barré syndrome, he must establish that he actually suffered from Guillain-Barré syndrome. In addition, Mr. Contreras must satisfy the three prongs from Althen, 418 F.3d 1274, 1278. For each of these aspects of Mr. Contreras's case, his burden of proof is the preponderance of the evidence.

### **B. Did Mr. Contreras Suffer from Guillain-Barré Syndrome in Addition to Transverse Myelitis?**

The first issue for resolution is identifying the disease or diseases afflicting Mr. Contreras. As noted in the Remand Decision, everyone agrees that he suffers from transverse myelitis. The second MRI revealed a lesion in Mr. Contreras's cervical spine. The radiologist interpreting the image (Dr. Lipson) and Mr. Contreras's treating neurologist (Dr. Lake) determined that this was evidence of transverse myelitis, not Guillain-Barré syndrome. Exhibit 7 at 167-71, 177-78. The discharge report from Miller's Children's Hospital identified Mr. Contreras's condition as "cervical transverse myelitis." Id. at 6.

In this litigation, Mr. Contreras obtained an affidavit from Dr. Garrett. Dr. Garrett was a member of the team of doctors who cared for Mr. Contreras during his approximately two-month stay at Miller's Children's Hospital. In the part that is pertinent to this aspect of the decision, Mr. Garrett averred that Mr. Contreras's disease was transverse myelitis. Exhibit 13 at 7.

Mr. Contreras also obtained two reports from Dr. Poser, of which the first presented Dr. Poser's opinion regarding the diseases affecting Mr. Contreras. Dr. Poser recognized that "[t]he original diagnosis of [GBS] . . . was then changed to cervical transverse myelitis as a result of a second MRI . . . on June 18, 2003," yet opined that "[f]rom the clinical examination and the MRI, it is clear that [Mr. Contreras] suffered from a combination of [GBS] . . . and . . . transverse myelitis." Exhibit 22 at 2, ¶ 3, 3, ¶ 4.

Dr. Poser's report, however, does not explain the bases for his opinion regarding diagnosis. Dr. Poser's assessment of the June 18, 2003 MRI conflicts directly with the view of Dr. Lipson, who saw the MRI as not consistent with GBS.

Dr. Poser's reference to Mr. Contreras's clinical course is also in conflict with the conclusions reached by Dr. Lake, who, after the June 18, 2003 MRI, consistently stated that Mr. Contreras suffered from transverse myelitis. Dr. Poser's report leaves unanswered the question of why Dr. Poser thinks that his opinion about Mr. Contreras's diagnosis is more accurate than the opinions reached by the team of doctors who cared for him. Despite the views of Dr. Lake, Dr. Lipson, and Dr. Garrett, Mr. Contreras claimed that the vaccinations caused him to suffer both transverse myelitis and Guillain-Barré syndrome. Pet. at 1; Pet'r's Resp., filed July 21, 2014, at 6-10.

In October 2005, Dr. Sladky wrote his first report. As to diagnosis, Dr. Sladky agreed with the treating doctors that the diagnosis was transverse myelitis. Exhibit I at 2. Both Dr. Garrett and Dr. Sladky discussed Mr. Contreras as suffering from transverse myelitis only, not transverse myelitis and Guillain-Barré syndrome. Thus, a complete disregard of Dr. Sladky's October 2005 report does not mean that the evidence concerning Mr. Contreras's diagnosis is on Mr. Contreras's side entirely.

More evidence favoring Mr. Contreras's position that he suffered from both transverse myelitis and GBS came when Mr. Contreras filed Dr. Steinman's first report. Dr. Steinman agreed with the diagnosis of transverse myelitis. Dr. Steinman also asserted "a secondary diagnosis of inflammatory polyradiculopathy/polyneuropathy [Guillain-Barre Syndrome] could also be made." Exhibit 55 at 2 (bracketed material in original). Dr. Steinman did not provide any basis for this conclusion.

Before Dr. Steinman had an opportunity to explain the basis for his suggestion that "a secondary diagnosis" of Guillain-Barré syndrome "could also be made," exhibit 55 at 2, the Federal Circuit issued Broekelschen. 618 F.3d at 1325. In Broekelschen, the Federal Circuit declared that in the circumstances of that case "it was appropriate in this case for the special master to first determine which injury was best supported by the evidence presented in the record before applying the Althen test." Broekelschen, 618 F.3d at 1346.<sup>26</sup> Broekelschen, a binding precedent, prompted attention to the correct diagnosis for Mr. Contreras. See order, issued Feb. 16, 2010 (requesting the parties set forth their positions regarding diagnosis in a pre-trial brief).

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<sup>26</sup> The Court held that "the Broekelschen exception to the general rule is inapplicable to this case." Contreras 2, 107 Fed. Cl. at 293.

In accord with the February 16, 2010 order, Mr. Contreras elicited testimony from Dr. Steinman about the disease or diseases that affected Mr. Contreras. Dr. Steinman stated that Mr. Contreras suffered from both transverse myelitis and Guillain-Barré syndrome. He testified on direct examination:

I think there are elements of both transverse myelitis and elements of Guillain-Barre. They're nice textbook entries where we talk about transverse myelitis as being an inflammatory disease of the spinal cord, and a nice textbook description[] of Guillain-Barre being an inflammatory disease of the peripheral nerve. The peripheral nerve ends at a certain varied definitive boundary with the central nervous system. However, the diseases unfortunately sometimes blend, and sometimes you can have elements of both inflammations in the central nervous system and inflammation in the peripheral nervous system. And those are the realities we have to deal with.

So Jesse Contreras had elements of both the transverse myelitis and the Guillain-Barre. . . . [It's] not possible to say he had only one or only the other. He had elements of both.

Tr. 118-19.

On cross-examination, Dr. Steinman was asked more about the basis for his opinion that Mr. Contreras suffered from Guillain-Barré syndrome. He conceded that none of the MRIs showed peripheral nerve involvement, although MRIs, according to Dr. Steinman, are not very useful in detecting peripheral problems. Tr. 184. Dr. Steinman agreed that a better method of testing peripheral nerves is an electromyogram (EMG), but the doctors did not order that test for Mr. Contreras. Tr. 185. Dr. Steinman's main support for his conclusion that Mr. Contreras also suffered from Guillain-Barré syndrome was Mr. Contreras's Babinski's response. Tr. 186, 255-56.<sup>27</sup>

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<sup>27</sup> Dr. Steinman's testimony about the Babinski response was, unfortunately, not as clear as it might have been. In this part of his testimony, Dr. Steinman stated:

(continued...)



Dr. Sladky disagreed with Dr. Steinman's conclusion about the significance of Mr. Contreras's downward going Babinski reflex. To summarize, Dr. Sladky opined that Mr. Contreras's results should be considered in context, such as who performed the test and when the test was performed and in the context of other evaluations. Tr. 281-86, 333-34. This testimony tended to balance, to some degree, Dr. Steinman's testimony. This testimony was one place in the Remand Decision where Dr. Sladky's opinion was credited and not redundant with other witness's testimony. Contreras 3, slip op. at 11 n.6, 2013 WL 6698382, at \*9 n.6.

If Dr. Sladky's testimony is removed, then Mr. Contreras's claim that he suffered from two diseases is more plausible. The meaningful evidence would include, on one hand, Dr. Steinman's report and testimony, and, on the other hand, the conclusions reached by Dr. Lake, Dr. Garrett, and the other doctors who treated Mr. Contreras. In this circumstance, the evidence still preponderates in favor of Mr. Contreras suffering from a single disease, transverse myelitis.

The Remand Decision found Dr. Lake's opinion "highly persuasive." Contreras 3, slip op. at 30, 2013 WL 6698382, at \*24. Similarly, the Remand Decision found that, among the witnesses who testified, Dr. Garrett was the "most persuasive." Contreras 3, slip op. at 30, 2013 WL 6698382, at \*25. This assessment did not depend (and does not depend) on Dr. Sladky's opinion. As pointed out in the Remand Decision, Dr. Lake saw Mr. Contreras almost every day for nearly three months. Dr. Lake, who performed a Babinski test on Mr. Contreras, specifically revised her tentative diagnosis that Mr. Contreras suffered from atypical Guillain-Barré syndrome due to the MRI results. Exhibit 7 at 1723. Her conclusion was persuasive to Dr. Babbitt, who, as a resident, was assisting Dr. Garrett in caring for Mr. Contreras. Id. at 123.

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[Guillain-Barré syndrome] was the presentation and the lack of Babinskis when the neurologist was eliciting the -- you know, usually if you have severe damage to the upper motor neurons, you're going to lose your plantar responses and you're going to have an upgoing Babinski response. And that wasn't seen. So again, I feel that this was a combination of Guillain-Barre and transverse myelitis. It doesn't perfectly fit into either category.

Tr. 186.

It appears that when Dr. Steinman used the phrase "upper motor neurons," he was referring to nerves in the spinal cord meaning transverse myelitis. But, Dr. Steinman did not explain (and was not asked to explain) how Mr. Contreras could have downgoing Babinski response if he were suffering from both transverse myelitis and Guillain-Barré syndrome.

The combined value of Dr. Lake and Dr. Garrett --- without any assistance from Dr. Sladky --- is greater than the opinion of Dr. Steinman. In most cases, the treating doctors' views about the disease that afflicts their patients are likely to be persuasive because the doctors have the advantage of touching, seeing, and hearing their patient.<sup>28</sup> Occasionally, doctors retained in the Vaccine Program have such a great amount of expertise in relatively arcane subjects that they are able to add insights about a person's diagnosis simply by reviewing the medical records. See, e.g., Barclay v. Sec'y of Health & Human Servs., No. 07-605V, 2014 WL 2925245, at \*1 (Fed. Cl. Spec. Mstr. Feb. 7, 2014) (respondent's doctor recommended genetic testing); cf. 42 U.S.C. § 300aa—13(b) (statements of treating doctors are not binding on special masters). But, Mr. Contreras's case is not one in which the treating doctors' diagnosis can be readily dismissed. Dr. Steinman's citation to the Babinski test provides a colorable basis for his suggestion that Dr. Lake and Dr. Garrett missed the fact that Mr. Contreras was suffering from not one, but two neurologic problems. But, ultimately, Dr. Lake's treatment of Mr. Contreras was thorough, caring, and professional. So was Dr. Garrett's. These factors, and not the opinion of Dr. Sladky, support the conclusion in the Remand Decision that Mr. Contreras did not suffer from Guillain-Barré syndrome.

The Remand Decision also discussed other evidence concerning the proper diagnosis, but this other evidence is weak. While Dr. Whitton, in his first report, accepted Dr. Poser's and Dr. Steinman's dual diagnosis, upon additional reflection, Dr. Whitton backed away from that conclusion. Compare exhibit L at 3 with exhibit N at 5. Dr. Poser, as discussed above, did not specify what factors in Mr. Contreras's MRI or his clinical presentation led Dr. Poser to add Guillain-Barré syndrome. Finally, Dr. Wagner's opinion that Mr. Contreras suffered from atypical Guillain-Barré syndrome, exhibit 6 at 5, was based upon less than five hours of observation and only one MRI. His opinion, although valuable in 2003, when he transferred Mr. Contreras to a higher care facility, cannot match the opinions of Doctors Lake and Garrett, who had much more information available to them.

The possibility that Mr. Contreras might suffer from "atypical" Guillain-Barré syndrome was a consideration very early in his hospitalizations. See exhibit 6 at 5 (Dr. Wagner); exhibit 7 at 1735 (Dr. Lake). Dr. Lake ceased to consider this possibility once she received the second MRI. Exhibit 7 at 1723.

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<sup>28</sup> Dr. Sladky, too, recognized the value of Dr. Garrett's opinion on diagnosis. Tr. 345.

In this litigation, Dr. Poser and Dr. Steinman have attempted to raise the dual diagnosis again. In doing so, they appear to be straining to fit a square peg into a round hole. Moreover, the persistence of Mr. Contreras's arguments appears to be overlooking the big picture of how his diagnosis fits with his claim for compensation. As the Remand Decision attempted to explain, if, on a strictly hypothetical basis, Mr. Contreras were persuasive in claiming that he suffered from both a central nervous system problem (transverse myelitis) and a peripheral nervous system problem (Guillain-Barré syndrome), see exhibit C (2002 IOM) at 28, Mr. Contreras's claim for compensation in the Vaccine Program would be more complicated. Mr. Contreras would be required to show how the hepatitis B vaccination can cause neurologic problems in two areas of the body involving two types of nerves within approximately one day of vaccination. See Tr. 447 (Dr. Whitton's opinion that one day is too short a latency period would not change depending upon the demyelinating disease).

### **C. Timing**

By far, the most important issue in this case has been the one-day interval between vaccination and the onset of neurological problems. This issue has been discussed throughout the case.

After the parties submitted briefs in 2011, Mr. Contreras was denied compensation. The sole and sufficient reason was that Mr. Contreras did not establish that the timing was medically appropriate for causation. Contreras 1, 2012 WL 1441315, at \*23-24. The Entitlement Decision did not evaluate either the second or third prong from Althen. The Entitlement Decision also did not discuss whether factors other than the vaccines could have caused Mr. Contreras's transverse myelitis.<sup>29</sup>

The analysis of Mr. Contreras's arguments regarding timing was divided into discrete sections. These were:

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<sup>29</sup> In Mr. Contreras's first motion for review, he argued that the exclusive focus on timing (Althen prong 3) was an error. The Court, however, disagreed and, stated that a special master may resolve a case based upon just one Althen prong. Contreras 2, 107 Fed. Cl. at 295. After the Court's first remand, the Federal Circuit has explicitly approved the resolution of a Vaccine Program case without an evaluation of all Althen prongs. Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012).

1. Steps Involved in Molecular Mimicry
2. How Much Time Does Molecular Mimicry Take
3. Observations of Molecular Mimicry in Medical Articles
  - a. Odoardi
  - b. Additional Medical Articles (Lafaille, Zamvil, Mensah-Brown, Mekala, Ufret-Vincentry)
  - c. Kakar Case Report
  - d. Summary Regarding Medical Articles
4. Petitioner's Explanation that Molecular Mimicry Can Occur in One Day
  - a. Tuberculin Response
  - b. Priming
5. Treating Doctors
  - a. Dr. Kyazze
  - b. Dr. Wagner
  - c. Dr. Garrett
6. Synopsis on Timing

The analysis largely, but not entirely, focused on the competing opinions of Dr. Steinman and Dr. Whitton. For example, the basic explanation for molecular mimicry came from Dr. Steinman upon which Dr. Whitton elaborated. In this section, Dr. Sladky was cited only in a footnote and not for any substantive information about molecular mimicry. Contreras 1, 2012 WL 1441315, at \*10 n.10.

In the second section, the Entitlement Decision relied primarily upon Dr. Whitton for finding that “at least five days is needed for molecular mimicry.” It found one step in the process of molecular mimicry that takes three days by itself and stated, “Dr. Whitton was superbly qualified to express [this] opinion.” This section also credited Dr. Whitton’s reliance on the blood-brain barrier and noted that “Dr. Steinman offered no persuasive response.” Contreras 1, 2012 WL 1441315, at \*11-12.

This section also cited Dr. Sladky’s opinion in three places. It quoted Dr. Sladky’s initial report. It also referenced Dr. Sladky’s opinion regarding the blood-brain barrier as a “see also” cite, supporting Dr. Whitton’s testimony. Finally, the summary paragraph mentioned Dr. Sladky’s opinion in conjunction with Dr. Whitton’s opinion. Id. at 12.

The Entitlement Decision’s third section on timing was a multi-part discussion about medical articles. The Odoardi article was a significant reason Mr.

Contreras was denied compensation, warranting a part by itself. Id. at 12 (stating “[t]he most important article about the timing of molecular mimicry was exhibit 118”). This discussion did not include any citations to Dr. Sladky, who had not testified about Odoardi. Although Dr. Steinman pointed to this article as an experiment in which an animal developed a central nervous system problem within one day of receiving an antigen that was roughly equivalent to a vaccination (see exhibit 105 (Supp’l Rep’t) at 7; Tr. 243-46, 589-90), the article, in fact, did not illustrate this chronology. The Entitlement Decision found persuasive Dr. Whitton’s assessment that Dr. Steinman “did not understand” the Odoardi experiment. Contreras 1, 2012 WL 1441315, at \*13 (quoting Tr. 633). Dr. Steinman’s misinterpretation of the article that appeared to be the most helpful article to Mr. Contreras’s claim severely diminished Dr. Steinman’s persuasiveness.

The next part discussed five medical articles. Three of them were cited by Dr. Steinman. Two (Mensah-Brown (exhibit D) and Mekala (exhibit K)) came from Dr. Sladky. Eliminating these two does not change the analysis because the remaining three articles also did not show a one-day interval.

The third part of the section about medical articles on timing was a discussion of a case report by Kakar. Exhibit 72. Kakar reported on a patient who received the hepatitis B vaccine and developed a condition like Guillain-Barré syndrome the next day. Id. The Entitlement Decision cited Dr. Sladky and Dr. Whitton for their views that case reports usually do not provide valuable information regarding causation. Contreras 1, 2012 WL 1441315, at \*16-17. Eliminating Dr. Sladky’s testimony would not affect the outcome because Dr. Whitton’s similar testimony would remain. Moreover, the value that Dr. Sladky, Dr. Whitton, or Dr. Steinman place upon any piece of evidence is not decisive because the special master, ultimately, must evaluate all the evidence. See Whitecotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence”).

While the witnesses’ comments about the (lack of) value about case reports may be helpful, the undersigned did not need Dr. Sladky to testify, as he did, that Kakar presents a sequence of events from which causality cannot be presumed. Tr. 298-99. The authors of the Kakar case report noted that one possibility was the patient’s “GBS was unrelated to the vaccine.” Exhibit 72 (Kakar) at 711. Thus,

even if Dr. Sladky's evidence were entirely excluded, Kakar would have minimal weight for the reasons Dr. Whitton explained. See Tr. 430.

The section on medical articles concludes with a short summary, which again mentions Dr. Sladky. However, in light of the overwhelming reliance on Dr. Whitton, the result would have been the same in the absence of Dr. Sladky.

The fourth section of the Entitlement Decision discusses two explanations for why Mr. Contreras could have reacted more quickly than expected by medical science: tuberculin and priming. For tuberculin, the Entitlement Decision often cited and eventually credited the testimony of Dr. Whitton. Although Dr. Sladky is occasionally mentioned, citations to Dr. Sladky are usually to his testimony as a supporting, not primary, authority. For priming, Dr. Sladky is not cited at all. Contreras 1, 2012 WL 1441315, at \*20-21.

The fifth section discusses the views of treating doctors whose testimony Mr. Contreras presented either by affidavit (Dr. Garrett) or by affidavit and orally (Dr. Kyazze and Dr. Wagner). This aspect did not cite Dr. Sladky. Contreras 1, 2012 WL 1441315, at \*21-23.

After Mr. Contreras filed a motion for review, the Court vacated the Entitlement Decision. Among other failures, the Entitlement Decision did "not convince the court that the special master considered all the relevant evidence in the record that bears upon Althen prong three." Contreras 2, 107 Fed. Cl. at 296. The Court stated "the special master committed legal error in failing to give the opinions of Dr. Wagner and Dr. Garrett significant weight in his analysis of the evidence relevant to Althen prong three." Id. at 300. The Court also stated the "special master erred when he crafted a higher standard of proof than that required in de Bazan." Id. at 303 (citation omitted). The Court also disagreed with the special master's reliance on Porter, which the Entitlement Decision had interpreted as finding a special master's attribution of little value for case reports not arbitrary and capricious. Id. at 304. Consequently, the Court remanded the case with specific instructions, including a re-analysis of Althen prong 3. Id. at 308-09.

In accord with these instructions, the Remand Decision re-evaluated the evidence regarding timing, organized into the following parts. This section began with a brief review of the previous adjudications, mentioning Dr. Sladky four times --- once as a matter of procedural history, once in the context of a summary of his testimony, and twice in conjunction with testimony from Dr. Whitton.

Next, there is a synopsis of 11 types of evidence. An asterisk marks the sections in which Dr. Sladky is mentioned.

- b) Synopsis of Evidence (\*)
  - (1) Dr. Wagner
  - (2) Dr. Garrett
  - (3) Dr. Cheung
  - (4) Dr. Poser
  - (5) Dr. Steinman
  - (6) Dr. Sladky (\*)
  - (7) Dr. Whitton
  - (8) Newly Cited Case Reports
  - (9) Other Case Reports
  - (10) Review Articles
  - (11) Animal Studies

The assessment of the evidence ran approximately four pages in which Dr. Sladky's testimony was cited twice. In the first place, Dr. Sladky's opinion was cited in conjunction with Dr. Whitton. The Remand Decision noted that Dr. Sladky had opined that a one-day onset was "virtually impossible." Contreras 3, slip op. at 59, 2013 WL 6698382, at \*46 (citing exhibit I at 3). The next sentence indicated that Dr. Whitton had opined that it was "'exceedingly unlikely' that Mr. Contreras could have developed an immune response to his vaccination within 24 hours." Id. (citing exhibit N at 9). The second place where Dr. Sladky was cited was in the context of describing the contents of the record. Id. at \*47. Neither citation to Dr. Sladky was consequential.

The Remand Decision found "the testimony of Dr. Whitton to be the most persuasive." Contreras 3, slip op. at 61, 2013 WL 6698382, at \*48. Two reasons for crediting Dr. Whitton's testimony were his study, the Whitmire article, that showed memory T cells in mice required at least three days to divide, and the Odoardi article. Id. (citing exhibit L, tab 31 (Jason K. Whitmire, Tentative T Cells: Memory Cells Are Quick to Respond, but Slow to Divide, 4 PLoS Pathogens e1000041 (2008)) at e1000042. Dr. Sladky did not enhance the value of the Whitmire article or the Odoardi article. He did not testify about them.

If all evidence originating with Dr. Sladky were struck, would the result change? The answer is no.

The fundamental problem with Mr. Contreras's case is that his evidence is not persuasive. Mr. Contreras bears the burden of "establish[ing] by a preponderance of the evidence that his onset of symptoms occurred within a timeframe for which it is medically acceptable to infer causation-in-fact." Contreras 2, 107 Fed. Cl. at 303. There is no dispute that the onset of symptoms occurred approximately 24 hours after vaccination. The ensuing question, therefore, becomes is 24 hours a "timeframe for which it is medically acceptable to infer causation-in-fact?"

Mr. Contreras's supporting evidence consists of the affidavit from Dr. Garrett, the affidavit and testimony from Dr. Wagner, the affidavits from Dr. Poser, and the affidavit and testimony from Dr. Steinman. Of these, Dr. Poser and Dr. Wagner contribute very little. Although each says that the timing was acceptable, neither presents any basis for the doctor's opinion. Special masters are not required to accept the unsupported testimony of an expert. Snyder, 88 Fed. Cl. at 742 (citing Gen. Elec. Co., 522 U.S. at 146); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing Gen. Elec. Co., 522 U.S. at 146).

On the face of it, Dr. Garrett and Dr. Steinman stand on ground that is more solid. They cite many case reports in which the administration of different vaccines preceded the onset of assorted illnesses. The details of the case reports were presented in the Entitlement Decision (Contreras 1, 2012 WL 1441315, at \*16-17), and the Remand Decision (Contreras 3, slip op. at 55-57, 2013 WL 6698382, at \*43-43). The details about vaccine / disease combination are largely irrelevant. The logical fallacy of attempting to draw causal conclusions from isolated reports can be temporarily set aside, too. For purposes of determining whether Dr. Garrett, or Dr. Steinman, or Dr. Garrett and Dr. Steinman were persuasive in opining that one day is a "medically acceptable" timeframe, the temporal interval in the case reports is most important.

Except for Kakar (exhibit 72), the interval is usually not close to one day. For example, Iniguez reported a case of transverse myelitis one week after a hepatitis B vaccination. Exhibit 47 (C. Iniguez et al., Acute transverse myelitis secondary to hepatitis B vaccination, 31(5) Rev. Neurol. 430 (2000)). How does Iniguez's report of a seven-day interval support Dr. Steinman, who cited Iniguez, in asserting that one day is medically acceptable? Iniguez and most of the other articles are entirely consistent with Dr. Whitton's opinion that, assuming that molecular mimicry actually explains how a vaccine can cause a demyelinating disease, the process of molecular mimicry probably takes five days.



After elimination of the case reports in which the onset is five days or longer, Dr. Garrett is similarly situated with Dr. Wagner and Dr. Poser.<sup>30</sup> Dr. Garrett asserted an opinion without any supporting basis. As a matter of law, the opinion of doctor who treats a person is not elevated to such a favored status that the special master must accept it. See 42 U.S.C. § 300aa—13(b); see also Ruiz, 2007 WL 5161754, at \*15 (stating “The fact that [a treating doctor] did not identify the hepatitis B vaccine as the cause of Ms. Ruiz’s psychological injury until well after his treatment relationship with petitioner had ended undermines the persuasiveness of his findings”). To be persuasive, Dr. Garrett does not have to dot every “i” and to cross every “t” because petitioners do not bear the burden of proving their case to a scientific certainty. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 872-73 (Fed. Cir. 1991). Yet, special masters may examine petitioner’s case to see whether the expert’s opinion is “sound.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994).

It might be argued that any examination of Dr. Garrett’s opinion is erroneous. After all, Dr. Garrett treated Mr. Contreras and “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citation and quotation marks omitted).

This argument, however, is belied by Bazan. There, a petitioner presented the opinion from her treating doctor that a repeat dose of the tetanus-diphtheria vaccine caused the onset of a demyelinating disease of the central nervous system, acute disseminated encephalomyelitis (“ADEM”), 11 hours later. The special master did not accept the opinion of this treating doctor and credited, instead, the opinion of the Secretary’s expert. On appeal, the Federal Circuit did not require the special master to defer to the opinion of the treating doctor. The Federal Circuit ruled that the special master’s finding regarding timing was not arbitrary or capricious. Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1352-53 (Fed. Cir. 2008).

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<sup>30</sup> Dr. Garrett cited an article written by Dr. Poser. Exhibit 13 at 11, ¶ 15 (citing exhibit 21 (Charles M. Poser, Neurologic syndromes that arise unpredictably, Consultant 45 (Jan. 1987))). In this 1987 article, Dr. Poser wrote that “[a]s a general rule, postvaccinal complications develop between one and six weeks after vaccination, although shorter periods have been reported... [T]his period can be as short as 12 to 24 hours.” Exhibit 21 (Posner) at 46-47. Dr. Poser provided no basis for this assertion. In addition, Dr. Poser does not specify what type of reaction could take place in 12 hours.

Although a simple review of the literature Dr. Garrett cited erodes the basis for his conclusion that one day is medically acceptable, Dr. Steinman's opinion is slightly stronger. Certainly, the Kakar article, which presents a sequence in which an Indian girl received a hepatitis B vaccine and then developed Guillain-Barré syndrome (or something like GBS) within 24 hours, supports Dr. Steinman's opinion that one day is medically acceptable. As Dr. Steinman testified, the presence of one case report makes the petitioner's case more persuasive than if there are no case reports. Tr. 164.

Two other articles are helpful to Mr. Contreras by reporting instances of demyelinating diseases that developed less than five days after vaccination. Douglas A. Kerr and Harold Ayetey cited a case report of transverse myelitis developing two days after influenza vaccination.<sup>31</sup> Exhibit N, tab 2 (Douglas A. Kerr & Harold Ayetey, Immunopathogenesis of Acute Transverse Myelitis, 15(3) Current Opinion in Neurology 339 (2002)). Sinsawaiwong presents an occasion on which hepatitis B vaccination preceded Guillain-Barré syndrome by three days. Exhibit 71 (Suwanna Sinsawaiwong & Pornpen Thampanitchawong, Guillain-Barré Syndrome Following Recombinant Hepatitis B Vaccine and Literature Review, 83 J. Med. Assoc'n Thai 1124 (2000)).

In addition, there are two reports of diseases that are not demyelinating diseases developing within one day of vaccination. These could lend some support if the difference between the reported injury and demyelinating disease is ignored. See exhibit 38 (B. Biacabe et al., A case report of fluctuant sensorineural hearing loss after hepatitis B vaccination, 24 Auris Nasus Larynx 457 (1997)) (hearing loss); and exhibit 45 (P.M. Bantz et al., Peripheral neurological symptoms after hepatitis B virus vaccination, 96 Q. J. Med. 611 (2003)) (vertigo and dysarthria).

Thus, the core of Mr. Contreras's case is Dr. Steinman's opinion as supported by at least one and potentially as many as five case reports. Does this constitute a persuasive case? If the record consisted of only this material, it could satisfy petitioner's burden. But, there is other evidence and a special master may consider evidence that contradicts a petitioner's case before determining whether the petitioner has met the burden of proof. Bazan, 539 F.3d at 1354.

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<sup>31</sup> Doctors Kerr and Ayetey noted that "such case reports must be viewed with caution, as it is entirely possible that two events occurred in close proximity by chance alone." Exhibit N, tab 2 at 341.

Here, the Secretary presented Dr. Whitton's report and testimony that effectively undermined Mr. Contreras's evidence, which came from Dr. Poser, Dr. Garrett, Dr. Wagner, and Dr. Steinman. Dr. Whitton persuasively showed that the process of a molecular mimicry reaction takes time. This time is measured in days, not hours. Hence, one day is not a medically acceptable timeframe to infer causation.

The Remand Decision also discussed theories by which Mr. Contreras proposed that his circumstances made relying upon the normally accepted minimal amount of time, five days, inappropriate. See Contreras 3, slip op. at 19-21, 2013 WL 6698382, at \*16-17. He suggested five factors could have accelerated his response: (1) previous exposures / priming, (2) his Hispanic ethnicity, (3) receipt of two vaccines at once, (4) the adjuvant, and (5) exposure to previous infections (the Epstein-Barr virus and mycoplasma pneumonia). The general impression left about these ideas was that Mr. Contreras and Dr. Steinman were throwing out ideas to see what would stick.

Mr. Contreras's presentation on each of these topics was discussed in the Remand Decision. The Remand Decision also cited the Secretary's evidence, which, at times, included Dr. Sladky. Even if Dr. Sladky's evidence were excluded,<sup>32</sup> Mr. Contreras has failed to present persuasive basis for finding that any of these proposed factors would make it possible for him to respond in one day, when normal people would require at least five days.

The Entitlement Decision closed its analysis about timing with a quotation from Dr. Whitton that a one-day onset presents a "black and white" issue. In Dr. Whitton's opinion, one day was well outside of any shades of grey about which reasonable people could differ. Contreras 1, 2012 WL 1441315, at \*23. On the first motion for review, the Court wondered if the situation were truly as stark as Dr. Whitton contended and suggested that if it were weighing the evidence in the first instance, the evidence might present a "close call." Contreras 2, 107 Fed. Cl. at 307. Contreras 3 attempted to address the Court's concern and cited Dr. Whitton as an example of an immunologist who understands the relevant biologic processes and the necessary amount of time for them. See Broekelschen, 618 F.3d at 1345 (holding "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Dr. Sladky's

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<sup>32</sup> Regarding Mr. Contreras's prior infections with Epstein-Barr virus and mycoplasma pneumonia, Dr. Sladky testified that they played no role in his neurologic disease. This testimony actually helps Mr. Contreras by eliminating potential alternative causes.

evidence added little to the analysis. Thus, eliminating the (meager) contributions from Dr. Sladky does not change the undersigned's view that the evidence is not close. The evidence preponderates in favor of finding that the minimal amount of time needed for molecular mimicry exceeds one day and is likely to be around five days.

#### **D. Theory**

The initial Entitlement Decision did not address the first prong of Althen because the finding that Mr. Contreras did not establish the third prong of Althen was sufficient to deny compensation. Contreras 1, 2012 WL 1441315, at \*1. As part of its instructions for the first remand, the Court ordered a consideration of prong one. Contreras 2, 107 Fed. Cl. at 295. The Remand Decision analyzed the relevant evidence, which included evidence from Dr. Sladky, and concluded that Mr. Contreras did not meet his burden of proof. Contreras 3, slip op. at 32-49, 2013 WL 6698382, at \*26-39. Contreras 3 organized the analysis of Althen prong 1 into the following sections with an asterisk marking the sections in which Dr. Sladky is mentioned:

1. Synopsis of Mr. Contreras's Evidence
  - a. Dr. Kyazze
  - b. Dr. Wagner
  - c. Dr. Garrett
  - d. Dr. Poser
  - e. Dr. Steinman
2. Synopsis of the Secretary's Evidence
  - a. Dr. Sladky \*
  - b. Dr. Whitton
3. Assessment of Evidence
  - a. Treating Doctors
  - b. Dr. Poser and Dr. Steinman
  - c. Daubert Analysis of Molecular Mimicry Theory
    - i. Whether the theory of molecular mimicry can be (and has been) tested
    - ii. Whether the theory or technique has been subject to peer review and publication
    - iii. Whether there is a known potential error rate and whether there are methods for controlling the error
    - iv. Whether the theory or technique enjoys general acceptance within a relevant scientific community \*

- v. Epidemiologic studies \*
- vi. Case Reports \*
- 4. Finding on Althen Prong One \*

As mentioned in the Remand Decision, Dr. Sladky's opinion played little role in this analysis. Dr. Sladky could not affect how the opinions of the treating doctors were weighed because he did not treat Mr. Contreras. The Remand Decision found that the opinions of Dr. Lake and Dr. Cheung were better informed than the opinions of Dr. Garrett and Dr. Wagner. Contreras 3, slip op. at 42, 2013 WL 6698382, at \*34. Dr. Lake and Dr. Cheung each indicated that the vaccinations did not cause Mr. Contreras's transverse myelitis. Exhibit 7 at 126, 147.

Dr. Sladky also did not affect the analysis of the first three Daubert factors. Mr. Contreras could have used the first two Daubert factors,<sup>33</sup> concerning testability and peer-review, to demonstrate the persuasiveness of Dr. Steinman's theory that the hepatitis B vaccine can cause transverse myelitis via molecular mimicry. See Veryzer v. Sec'y of Health & Human Servs., No. 06-522V, 2010 WL 2507791, at \*8 n.14 (Fed. Cl. Spec. Mstr. June 15, 2010) (quoting In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 744 (3d Cir. 1994)), mot. for rev. denied, 100 Fed. Cl. 344 (2011), aff'd without op., 475 Fed. Appx. 765 (Fed. Cir. 2012); Robles v. Sec'y of Health & Human Servs., No. 90-3001V, 2000 WL 748169, at \*2 n.10 (Fed. Cl. Spec. Mstr. May 19, 2000) (quoting Daubert, at 1316). Mr. Contreras did not present any supporting evidence. Dr. Sladky did not contribute to the lack of evidence from Mr. Contreras. Thus, the same result would have been reached even if there were no evidence from Dr. Sladky.

For the fourth Daubert factor, concerning general acceptance, Dr. Sladky's testimony actually helped Mr. Contreras. Dr. Sladky's concession on this factor, in turn, was mentioned as part of the overall finding. Contreras 3, slip op. at 49, 2013 WL 6698382, at \*38-39. Striking Dr. Sladky's testimony would weaken this specific aspect of Mr. Contreras's case.

The next factor, epidemiological studies, is a place where Dr. Sladky's evidence played some role. Dr. Sladky was the expert who originally placed into the record two studies the Remand Decision discussed, exhibit G (Touze) and

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<sup>33</sup> The third Daubert factor (error rate) does not apply to molecular mimicry.

exhibit H (Zipp). See exhibit I (Dr. Sladky's Oct. 21, 2005 report) at 4.<sup>34</sup> To avoid any dispute about the scope of the Court's instruction for removing Dr. Sladky's evidence, the Touze and Zipp articles will be disregarded.

Removing Touze and Zipp does not eliminate all epidemiological studies. Dr. Whitton cited a very important study by Mikaeloff. Exhibit L, tab 29 (Yann Mikaeloff et al., Hepatitis B vaccine and the risk of relapse after a first childhood episode of CNS inflammatory demyelination, 130 Brain 1105 (2007)). The Mikaeloff article was informative because these researchers studied 356 people who had experienced an episode of demyelination in their central nervous system before age 16. These participants were given a dose of the hepatitis B vaccine and followed for more than five years on average to see whether they had a relapse lasting more than 24 hours. The authors found that the hepatitis B vaccine "was not associated with a significant increase in the risk of relapse." Exhibit L, tab 29 (Mikaeloff) at 1108.

In addition to Mikaeloff, Dr. Whitton cited other epidemiological studies, although these were not as relevant. These studies analyzed a possible connection between vaccinations and other neurological diseases, such as multiple sclerosis and Guillain-Barré syndrome. See Contreras 3, slip op. at 39 n.29, 2013 WL 6698382, at \*31 n.29.

The sixth factor (case reports) also did not depend on Dr. Sladky's evidence. Dr. Sladky was cited as providing testimony that supported a statement that case reports may signal the need for additional study. Although the Remand Decision cited Dr. Sladky, special masters are very familiar with this concept.

The role of case reports as a signal was part of a more basic question concerning whether routine case reports provide meaningful information on which an informed judgment on causation may be made. The Remand Decision cited both Dr. Sladky and Dr. Whitton as people who find case reports carry relatively

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<sup>34</sup> The 2002 IOM report, which the Secretary had placed into evidence before Dr. Sladky's report, cited Touze and Zipp. Exhibit C (2002 IOM) at 57, 61. After Dr. Sladky's report, Dr. Steinman also cited to Touze and Zipp and Mr. Contreras submitted these studies as exhibits 75 and 76. Conceivably, even if Dr. Sladky had not cited Touze and Zipp, Dr. Steinman could have presented the epidemiological studies in accord with an expert's duty to present all relevant information to the judicial official. However, a voluntary presentation seems unlikely as Dr. Steinman has not previously cited Touze and Zipp in relatively similar circumstances.

little value. The Remand Decision also noted that Dr. Poser and Dr. Steinman, contrastingly, more readily valued case reports.

Ultimately, the opinion of any witness, including Dr. Sladky, about the strength or weakness of the evidence is not particularly important. The views of Dr. Steinman, Dr. Whitton, Dr. Poser, and Dr. Sladky are interesting because these people are educated and trained in medicine. Thus, the undersigned considers and reflects on those informed views in weighing the evidence. But, at the end of the day, “Congress made clear that the initial decision in these cases was the Special Master’s.” Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 962 (Fed. Cir. 1993).

As suggested in the Remand Decision, the undersigned chooses to give routine case reports little, if any, weight in determining causation. The undersigned has reached this conclusion after hearing not only the testimony of Dr. Sladky, Dr. Whitton, and Dr. Steinman, but also similar testimony from many doctors in many different hearings. See Porter v. Sec’y of Health & Human Servs., No. 99-639V, 2008 WL 4483740, at \*13 (Fed. Cl. Spec. Mstr. Oct. 2, 2008) (citing cases), mot. for rev. granted sub nom., Rotoli, 89 Fed. Cl. at 86-87, reinstated, Porter, 663 F.3d at 1254; Tiufekchiev v. Sec’y of Health & Human Servs., No. 05-437V, 2008 WL 3522297, at \*9 (Fed. Cl. Spec. Mstr. July 24, 2008) (quoting testimony from petitioner’s expert and citing cases). The undersigned has also considered --- and the Remand Decision cited --- the teachings from the Reference Manual on Scientific Evidence, published by the Federal Judicial Center. In addition, numerous cases in which plaintiffs claim exposure to a substance caused them harm have also discussed case reports. These, too, have affected the undersigned’s orientation to the usefulness of case reports.

Against this background, Dr. Sladky’s testimony that case reports do not provide meaningful information about causation amounts to little more than a drop in a bucket. Even in the absence of Dr. Sladky’s evidence, the undersigned would have assessed the case reports the same way. Although an appellate tribunal may determine that the weight the undersigned assigned to case reports was arbitrary and capricious (but see Porter, 663 F.3d at 1254 (ruling that the weight given to the evidence including case reports was not arbitrary or capricious)); that finding would be a determination about the undersigned’s weighing of the evidence, not Dr. Sladky’s weighing of the evidence.

On the whole, striking Dr. Sladky’s evidence does not change the outcome regarding Althen prong one. The main weakness in Mr. Contreras’s case was that

he failed to show the persuasiveness of Dr. Steinman's theory as measured against the Daubert factors. Dr. Steinman's theory that the hepatitis B vaccine can cause transverse myelitis via molecular mimicry is a plausible construct. But, plausibility does not satisfy Mr. Contreras's burden and the Secretary does not bear the burden of establishing that a petitioner's theory is impossible. See Moberly, 592 F.3d at 1322. The Remand Decision cited evidence from Dr. Sladky (Touze and Zipp) because those studies further undermined Dr. Steinman's theory that molecular mimicry can explain how the hepatitis B vaccine can cause transverse myelitis. But, striking those epidemiological studies does not strengthen Mr. Contreras's case, especially since another epidemiological study remains. In other words, Mr. Contreras needed to have more positive support for Dr. Steinman's theory.<sup>35</sup> Subtracting negative evidence does not equal adding positive evidence.

### **E. Althen Prong 2**

The remaining Althen prong is the second. Because Mr. Contreras has not established through preponderant evidence that the hepatitis B vaccine can cause transverse myelitis (prong 1) and has not established that his transverse myelitis arose in time for which it is medically acceptable to infer causation (prong 3), he cannot establish "a logical sequence" between the vaccination and his transverse myelitis. Nonetheless, in accord with the Court's instructions, the evidence regarding this element is again reviewed without any consideration of Dr. Sladky's evidence.

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<sup>35</sup> Saying that Mr. Contreras required more evidence to demonstrate the persuasiveness of Dr. Steinman's theory is not the same as saying that Mr. Contreras had to establish Dr. Steinman's theory to a level of medical certainty. See La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 201 (2013) (the petitioner's expert "could not back up his hypothesis with a reliable medical or scientific explanation. . . . [The special master] quite properly required petitioner to carry her burden to bring forward a reliable or scientific explanation"), aff'd, 746 F.3d 1334, 1340 (Fed. Cir. 2014); Langland v. Sec'y of Health & Human Servs., 109 Fed. Cl. 421, 441 (2013) ("the Special Master did not commit a legal error by requiring a sufficiently-detailed explanation" of how a vaccine can cause a disease); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 819 (2013) ("the mere existence" of expert testimony about a theory "is insufficient to satisfy the burden of showing a 'persuasive' medical theory --- this theory must also preponderate"). Petitioners are required to present preponderant cases, not certain cases. Hodges, 9 F.3d at 961-62 ("[t]he fact that the opinion of petitioner's doctors was rejected does not mean that the Special Master was demanding scientific certainty; he might simply have been demanding some degree of acceptable scientific support when concluding that the [petitioners'] claim for causation in-fact was not supported by a preponderance of the evidence").



The Remand Decision addressed two types of evidence. The first type was reports from treating doctors. The Remand Decision did not find persuasive the testimony from Dr. Garrett and Dr. Wagner, and found more persuasive the statements that Dr. Babbitt, Dr. Cheung, and Dr. Lake made during their course of treating Mr. Contreras. Dr. Sladky's evidence played no role regarding this first type of evidence.

The second type of evidence was evidence of alternative cause as the Court directed. See Contreras 2, 107 Fed. Cl. at 296-97. The Remand Decision cited Dr. Sladky as not identifying any other potential cause. Contreras 3, slip op. at 73, 2013 WL 6698382, at \*57 (citing Tr. 351). Dr. Sladky's position was not special. The treating doctors did not identify any possible other cause. See exhibit 7 at 6-8 (discharge report); exhibit 13 (Dr. Garrett's affidavit) at 6-7 ¶ 12. Thus, even if Dr. Sladky's testimony were eliminated, there would still be no other alternative causal factor.

As discussed in the Remand Decision, the lack of a known alternative factor does not mean that the vaccinations caused Mr. Contreras's transverse myelitis. See Caves, 100 Fed. Cl. at 141; Fadelalla v. United States, 45 Fed. Cl. 196, 201 (1999). The lack of alternative factors might be more significant if Mr. Contreras had established that the hepatitis B vaccine can cause transverse myelitis and if Mr. Contreras had established that the hepatitis B vaccine can cause transverse myelitis in one day. But, for the reasons explained above in sections IV.C-D, Mr. Contreras has not established these predicates even if Dr. Sladky's evidence is excluded.

In the absence of a finding that the vaccinations caused Mr. Contreras's transverse myelitis, the cause of his tragic disease remains unknown. See Tr. 263-64 (Dr. Steinman: the vast majority of TM cases are idiopathic).

## **V. Additional Comments**

On a personal level, Mr. Contreras's episode with transverse myelitis was a terrible ordeal. The attention given to him by Dr. Wagner, Dr. Garrett, Dr. Lake and other doctors sustained him during a perilous time. It is fortunate that he has recovered as much as he has, even though his health remains impaired. He deserves sympathy for his suffering.

The process of litigating this Vaccine Program claim is, almost certainly, bringing more disappointment to Mr. Contreras. For reasons not entirely within Mr. Contreras's control, the litigation has been an unduly lengthy process. The fact that the most recent delay is to address misconduct by the Secretary's expert

witness may be especially irritating. Mr. Contreras may understandably question how the Secretary can prevail after relying upon a witness who was deceptive about his background.

This Decision has attempted to demonstrate that the penalty for a witness's deception is not always the striking of the witness's testimony. On occasion, a reasonable remedy is to bar the witness from testifying and to strike all evidence associated with that witness. The chief special master in Raymo took a similar approach for Dr. Sladky by refusing to give his testimony any weight. But, another special master kept Dr. Sladky's evidence in the record. Roberts, 2013 WL 5314698, at \*9. These two cases demonstrate that there can be more than one (correct) answer to the question "what should happen to Dr. Sladky's evidence?"

As discussed in section II.A, the response in the Remand Decision was closer to Roberts than Raymo. However, the overall outcome in Mr. Contreras is the opposite of the outcome in Roberts and Raymo. How can these disparate outcomes be reconciled?

The evidence among the three cases is much different. In Roberts, the primary dispute was whether the vaccinee suffered from transverse myelitis as three of her treating doctors testified or suffered from an embolism as the Secretary's experts, Dr. Sladky and a neuroradiologist, testified. The special master credited the views of the treating doctors. She found Dr. Sladky's testimony not "as reliable and persuasive as the testimony" of petitioner's treating doctors for multiple reasons, one of which was Dr. Sladky's failure to disclose his licensing problems. Roberts, 2013 WL 5314698, at \*9. The special master also considered that the Secretary's neuroradiologist thought the vaccinee's imaging presented a close call between the two diagnoses. Thus, the balance of the evidence was on petitioners' side.

In Raymo, after the chief special master disregarded Dr. Sladky's testimony, the Secretary had "no other witnesses to counter Dr. Kinsbourne's theory that [the vaccinee] suffered from [acute transverse myelitis]." Raymo, 2014 WL 1092274, at \*2 n.9. The chief special master returned to the absence of evidence in beginning her analysis. She stated:

Because I attach no weight to the opinions of Drs. Sladky and Becker, Dr. Kinsbourne's opinion is largely un rebutted. Although I have considered the expert report and testimony of Dr. Gill, her evidence was almost

exclusively focused on demonstrating that Dr. Becker's theory regarding a vascular cause for [the vaccinee's] infarction was unsound, and thus is not relevant to the causation theory still before me.

Id. at 17 (footnote omitted). The “largely un rebutted” testimony from Dr. Kinsbourne persuaded the chief special master to find in petitioner’s favor.

Here, even if Dr. Sladky’s testimony were excluded, Mr. Contreras’s evidence is far from “largely un rebutted.” There is conflicting evidence on virtually every point. For example, Dr. Garrett’s opinion about the diagnosis does not match the opinions of Dr. Steinman and Dr. Poser.

The most prominent example of a conflict in evidence, independent of Dr. Sladky’s evidence, concerns timing. Here, the contest was largely between Dr. Steinman and Dr. Whitton. Dr. Whitton persuasively explained why a one-day interval between vaccination and the onset of neurologic symptoms associated with a lesion in the cervical spine was not biologically possible. Dr. Whitton’s position is in accord with the 1994 IOM report (exhibits A, F, and V). In contrast, Dr. Steinman could present only weak and unpersuasive support for his opinion that all the steps associated with molecular mimicry can happen within one day. Dr. Whitton’s testimony on timing was very strong and persuasive, making Dr. Sladky’s testimony on this topic redundant. See Hulbert v. Sec’y of Health & Human Servs., 49 Fed. Cl. 485, 490 (2001) (ruling that special master did not commit reversible error in declining to strike one expert’s testimony when the denial of compensation rested upon the testimony of another expert), aff’d, 35 Fed. Appx 899 (Fed. Cir. 2002).

## **VI. Conclusion**

Contreras 4, 116 Fed. Cl. at 484, remanded this case for a discussion of three issues. First, the Court ordered an assessment of Dr. Sladky’s credibility and reliability. Dr. Sladky, despite some misleading testimony about his qualifications, remained credible enough to offer opinions. His opinions were based upon a reliable methodology. In conjunction with these findings, Mr. Contreras’s post-remand motion to strike Dr. Sladky’s evidence is denied. Second, the Court ordered a comparison of credibility among the different people who testified either by affidavit or in person. Dr. Sladky falls near the bottom of the list and Dr. Whitton is at the top. Third, the Court ordered an analysis of the evidence remaining after Dr. Sladky’s evidence was removed. This analysis does not

change the outcome of the case. Mr. Contreras would still have failed to establish the Althen prongs.

Mr. Contreras remains not entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. The Clerk's Office is also instructed to provide this decision to the presiding judge pursuant to Vaccine Rule 28.1(a).

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master